PART 70 OPERATING PERMIT
OFFICE OF AIR QUALITY

Schwarz Pharma Manufacturing, Inc.
1101 C Avenue West
Seymour, Indiana 47274

(herein known as the Permittee) is hereby authorized to operate subject to the conditions contained herein, the source described in Section A (Source Summary) of this permit.

This permit is issued in accordance with 326 IAC 2 and 40 CFR Part 70 Appendix A and contains the conditions and provisions specified in 326 IAC 2-7 as required by 42 U.S.C. 7401, et. seq. (Clean Air Act as amended by the 1990 Clean Air Act Amendments), 40 CFR Part 70.6, IC 13-15 and IC 13-17.

Operation Permit No.: T071-7162-00023	
Original signed by Issued by: Janet G. McCabe, Assistant Commissioner Office of Air Quality	Issuance Date: March 25, 2002 Expiration Date: March 25, 2007

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SECTION A SOURCE SUMMARY

This permit is based on information requested by the Indiana Department of Environmental Management (IDEM), Office of Air Quality (OAQ). The information describing the source contained in conditions A.1 through A.3 is descriptive information and does not constitute enforceable conditions. However, the Permittee should be aware that a physical change or a change in the method of operation that may render this descriptive information obsolete or inaccurate may trigger requirements for the Permittee to obtain additional permits or seek modification of this permit pursuant to 326 IAC 2, or change other applicable requirements presented in the permit application.

A.1 General Information [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

The Permittee owns and operates batch pharmaceutical manufacturing facility producing liquid, capsule, and tablet pharmaceuticals.

Responsible Official:	Leo Katalinas
Source Address:	1101 C Avenue West, Seymour, Indiana 47274
Mailing Address:	1101 C Avenue West, Seymour, Indiana 47274
SIC Code:	2834
County Location:	Jackson
Source Location Status:	Attainment for all criteria pollutants
Source Status:	Part 70 Permit Program Minor Source, under PSD; Major Source, Section 112 of the Clean Air Act

A.2 Emission Units and Pollution Control Equipment Summary [326 IAC 2-7-4(c)(3)] [326 IAC 2-7-5(15)]

This stationary source consists of the following emission units and pollution control devices:

(a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000.

(b) One (1) tablet manufacturing department, constructed in 1993, consisting of

(1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) electric production ovens, equipped with a baghouse for particulate matter control, identified as V2.

(2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with a baghouse for particulate matter control, identified as V4.

(3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate mater control, identified as V6 and V9.

(c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.

(d) One (1) Phase IIIA production area, identified as emission unit 02 (EU-02). This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse EU-02. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with two (2) baghouses, identified as V7 and V8. These units were constructed in 2000.

(e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.

(f) One (1) Colyte production area (identified as emission unit 01 (EU-01)), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse EU-01.

A.3 Specifically Regulated Insignificant Activities [326 IAC 2-7-1(21)] [326 IAC 2-7-4(c)] [326 IAC 2-7-5(15)]

This stationary source also includes the following insignificant activities which are specifically regulated, as defined in 326 IAC 2-7-1(21):

(a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed between 1985 and 2000, including:

(1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4];

(2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4]; and

(b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment [326 IAC 6-3].

(c) Paved and unpaved roads and parking lots with public access [326 IAC 6-4].

(d) Other categories with emissions below insignificant thresholds:

(1) A liquid pharmaceutical manufacturing facility, consisting of liquid blending, filtration, and packaging, emitting less than three (3) pounds per hour of VOC.

(2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as V1. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

A.4 Part 70 Permit Applicability [326 IAC 2-7-2]

This stationary source is required to have a Part 70 permit by 326 IAC 2-7-2 (Applicability) because it is a major source, as defined in 326 IAC 2-7-1(22).

SECTION B GENERAL CONDITIONS

B.1 Definitions [326 IAC 2-7-1]

Terms in this permit shall have the definition assigned to such terms in the referenced regulation. In the absence of definitions in the referenced regulation, the applicable definitions found in the statutes or regulations (IC 13-11, 326 IAC 1-2 and 326 IAC 2-7) shall prevail.

B.2 Permit Term [326 IAC 2-7-5(2)][326 IAC 2-1.1-9.5]

This permit is issued for a fixed term of five (5) years from the original date, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date.

B.3 Enforceability [326 IAC 2-7-7]

Unless otherwise stated, all terms and conditions in this permit, including any provisions designed to limit the source's potential to emit, are enforceable by IDEM, the United States Environmental Protection Agency (U.S. EPA) and by citizens in accordance with the Clean Air Act.

B.4 Termination of Right to Operate [326 IAC 2-7-10] [326 IAC 2-7-4(a)]

The Permittee's right to operate this source terminates with the expiration of this permit unless a timely and complete renewal application is submitted at least nine (9) months prior to the date of expiration of the source's existing permit, consistent with 326 IAC 2-7-3 and 326 IAC 2-7-4(a).

B.5 Severability [326 IAC 2-7-5(5)]

The provisions of this permit are severable; a determination that any portion of this permit is invalid shall not affect the validity of the remainder of the permit.

B.6 Property Rights or Exclusive Privilege [326 IAC 2-7-5(6)(D)]

This permit does not convey any property rights of any sort or any exclusive privilege.

B.7 Duty to Supplement and Provide Information [326 IAC 2-7-4(b)] [326 IAC 2-7-5(6)(E)] [326 IAC 2-7-6(6)]

(a) The Permittee, upon becoming aware that any relevant facts were omitted or incorrect information was submitted in the permit application, shall promptly submit such supplementary facts or corrected information to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The Permittee shall furnish to IDEM, OAQ, within a reasonable time, any information that IDEM, OAQ, may request in writing to determine whether cause exists for modifying, revoking and reissuing, or terminating this permit, or to determine compliance with this permit. The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34). Upon request, the Permittee shall also furnish to IDEM, OAQ, copies of records required to be kept by this permit or, for information claimed to be confidential, the Permittee may furnish such records directly to the U. S. EPA along with a claim of confidentiality. [326 IAC 2-7-5(6)(E)]

(c) The Permittee may include a claim of confidentiality in accordance with 326 IAC 17.1. When furnishing copies of requested records directly to U. S. EPA, the Permittee may assert a claim of confidentiality in accordance with 40 CFR 2, Subpart B.

B.8 Compliance with Permit Conditions [326 IAC 2-7-5(6)(A)] [326 IAC 2-7-5(6)(B)]

(a) The Permittee must comply with all conditions of this permit. Noncompliance with any provisions of this permit is grounds for:

(1) Enforcement action;

(2) Permit termination, revocation and reissuance, or modification; or

(3) Denial of a permit renewal application.

(b) Noncompliance with any provisions of this permit, except any provision specifically designated as not federally enforceable, constitutes a violation of the Clean Air Act.

(c) It shall not be a defense for the Permittee in an enforcement action that it would have been necessary to halt or reduce the permitted activity in order to maintain compliance with the conditions of this permit.

(d) An emergency does constitute an affirmative defense in an enforcement action provided the Permittee complies with the applicable requirements set forth in Section B, Emergency Provisions.

B.9 Certification [326 IAC 2-7-4(f)] [326 IAC 2-7-6(1)] [326 IAC 2-7-5(3)(C)]

(a) Where specifically designated by this permit or required by an applicable requirement, any application form, report, or compliance certification submitted shall contain certification by a responsible official of truth, accuracy, and completeness. This certification shall state that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

(b) One (1) certification shall be included, using the attached Certification Form, with each submittal requiring certification.

(c) A responsible official is defined at 326 IAC 2-7-1(34).

B.10 Annual Compliance Certification [326 IAC 2-7-6(5)]

(a) The Permittee shall annually submit a compliance certification report which addresses the status of the source's compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. The initial certification shall cover the time period from the date of final permit issuance through December 31 of the same year. All subsequent certifications shall cover the time period from January 1 to December 31 of the previous year, and shall be submitted in letter form no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Air Enforcement Branch - Indiana (AE-17J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

(b) The annual compliance certification report required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the

shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

(c) The annual compliance certification report shall include the following:

(1) The appropriate identification of each term or condition of this permit that is the basis of the certification;

(2) The compliance status;

(3) Whether compliance was continuous or intermittent;

(4) The methods used for determining the compliance status of the source, currently and over the reporting period consistent with 326 IAC 2-7-5(3); and

(5) Such other facts, as specified in Sections D of this permit, as IDEM, OAQ, may require to determine the compliance status of the source.

The submittal by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

B.11 Preventive Maintenance Plan [326 IAC 2-7-5(1),(3) and (13)] [326 IAC 2-7-6(1) and (6)] [326 IAC 1-6-3]

(a) If required by specific condition(s) in Section D of this permit, the Permittee shall prepare and maintain Preventive Maintenance Plans (PMPs) within ninety (90) days after issuance of this permit, including the following information on each facility:

(1) Identification of the individual(s) responsible for inspecting, maintaining, and repairing emission control devices;

(2) A description of the items or conditions that will be inspected and the inspection schedule for said items or conditions; and

(3) Identification and quantification of the replacement parts that will be maintained in inventory for quick replacement.

If, due to circumstances beyond the Permittee's control, the PMPs cannot be prepared and maintained within the above time frame, the Permittee may extend the date an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The PMP and the PMP extension notification do not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The Permittee shall implement the PMPs as necessary to ensure that failure to implement a PMP does not cause or contribute to a violation of any limitation on emissions or potential to emit.

(c) A copy of the PMPs shall be submitted to IDEM, OAQ, upon request and within a reasonable time, and shall be subject to review and approval by IDEM, OAQ. IDEM, OAQ, may require the Permittee to revise its PMPs whenever lack of proper

maintenance causes or contributes to any violation. The PMP does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

d. Records of preventive maintenance shall be retained for a period of at least five (5) years. These records shall be kept at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

B.12 Emergency Provisions [326 IAC 2-7-16]

(a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation.

(b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:

(1) An emergency occurred and the Permittee can, to the extent possible, identify the causes of the emergency;

(2) The permitted facility was at the time being properly operated;

(3) During the period of an emergency, the Permittee took all reasonable steps to minimize levels of emissions that exceeded the emission standards or other requirements in this permit;

(4) For each emergency lasting one (1) hour or more, the Permittee notified IDEM, OAQ, within four (4) daytime business hours after the beginning of the emergency, or after the emergency was discovered or reasonably should have been discovered;

Telephone Number: 1-800-451-6027 (ask for Office of Air Quality, Compliance Section), or
Telephone Number: 317-233-5674 (ask for Compliance Section)
Facsimile Number: 317-233-5967

(5) For each emergency lasting one (1) hour or more, the Permittee submitted the attached Emergency Occurrence Report Form or its equivalent, either by mail or facsimile to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

within two (2) working days of the time when emission limitations were exceeded due to the emergency.

The notice fulfills the requirement of 326 IAC 2-7-5(3)(C)(ii) and must contain the following:

(A) A description of the emergency;

(B) Any steps taken to mitigate the emissions; and

(C) Corrective actions taken.

The notification which shall be submitted by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(6) The Permittee immediately took all reasonable steps to correct the emergency.

(c) In any enforcement proceeding, the Permittee seeking to establish the occurrence of an emergency has the burden of proof.

(d) This emergency provision supersedes 326 IAC 1-6 (Malfunctions). This permit condition is in addition to any emergency or upset provision contained in any applicable requirement.

(e) IDEM, OAQ, may require that the Preventive Maintenance Plans required under 326 IAC 2-7-4-(c)(10) be revised in response to an emergency.

(f) Failure to notify IDEM, OAQ, by telephone or facsimile of an emergency lasting more than one (1) hour in accordance with (b)(4) and (5) of this condition shall constitute a violation of 326 IAC 2-7 and any other applicable rules.

(g) If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

B.13 Permit Shield [326 IAC 2-7-15] [326 IAC 2-7-20] [326 IAC 2-7-12]

(a) Pursuant to 326 IAC 2-7-15, the Permittee has been granted a permit shield. The permit shield provides that compliance with the conditions of this permit shall be deemed in compliance with any applicable requirements as of the date of permit issuance, provided that either the applicable requirements are included and specifically identified in this permit or the permit contains an explicit determination or concise summary of a determination that other specifically identified requirements are not applicable. The Indiana statutes from IC 13 and rules from 326 IAC, referenced in conditions in this permit, are those applicable at the time the permit was issued. The issuance or possession of this permit shall not alone constitute a defense against an alleged violation of any law, regulation or standard, except for the requirement to obtain a Part 70 permit under 326 IAC 2-7 or for applicable requirements for which a permit shield has been granted.

This permit shield does not extend to applicable requirements which are promulgated after the date of issuance of this permit unless this permit has been modified to reflect such new requirements.

(b) If, after issuance of this permit, it is determined that the permit is in nonconformance with an applicable requirement that applied to the source on the date of permit issuance, IDEM, OAQ, shall immediately take steps to reopen and revise this permit and issue a compliance order to the Permittee to ensure expeditious compliance with the applicable requirement until the permit is reissued. The permit shield shall continue in effect so long as the Permittee is in compliance with the compliance order.

(c) No permit shield shall apply to any permit term or condition that is determined after issuance of this permit to have been based on erroneous information supplied in the permit application. Erroneous information means information that the Permittee knew to be false, or in the exercise of reasonable care should have been known to be false, at the time the information was submitted.

(d) Nothing in 326 IAC 2-7-15 or in this permit shall alter or affect the following:

(1) The provisions of Section 303 of the Clean Air Act (emergency orders), including the authority of the U.S. EPA under Section 303 of the Clean Air Act;

(2) The liability of the Permittee for any violation of applicable requirements prior to or at the time of this permit's issuance;

(3) The applicable requirements of the acid rain program, consistent with Section 408(a) of the Clean Air Act; and

(4) The ability of U.S. EPA to obtain information from the Permittee under Section 114 of the Clean Air Act.

(e) This permit shield is not applicable to any change made under 326 IAC 2-7-20(b)(2) (Sections 502(b)(10) of the Clean Air Act changes) and 326 IAC 2-7-20(c)(2) (trading based on State Implementation Plan (SIP) provisions).

(f) This permit shield is not applicable to modifications eligible for group processing until after IDEM, OAQ, has issued the modifications. [326 IAC 2-7-12(c)(7)]

(g) This permit shield is not applicable to minor Part 70 permit modifications until after IDEM, OAQ, has issued the modification. [326 IAC 2-7-12(b)(7)]

B.14 Prior Permits Superseded [326 IAC 2-1.1-9.5]

(a) All terms and conditions of previous permits issued pursuant to permitting programs approved into the state implementation plan have been either

(1) incorporated as originally stated,

(2) revised, or

(3) deleted

by this permit.

(b) All previous registrations and permits are superseded by this permit.

B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-7-5(3)(C)(ii)]

(a) Deviations from any permit requirements (for emergencies see Section B - Emergency Provisions), the probable cause of such deviations, and any response steps or preventive measures taken shall be reported to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

using the attached Quarterly Deviation and Compliance Monitoring Report, or its equivalent. A deviation required to be reported pursuant to an applicable requirement that exists independent to this permit, shall be reported according to the schedule stated in the applicable requirement and does not need to be included in this report.

The Quarterly Deviation and Compliance Monitoring Report does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

(b) A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit.

(c) Emergencies shall be included in the Quarterly Deviation and Compliance Monitoring Report.

B.16 Permit Modification, Reopening, Revocation and Reissuance, or Termination [326 IAC 2-7-5(6)(C)] [326 IAC 2-7-8(a)] [326 IAC 2-7-9]

(a) This permit may be modified, reopened, revoked and reissued, or terminated for cause. The filing of a request by the Permittee for a Part 70 permit modification, revocation and reissuance, or termination, or of a notification of planned changes or anticipated noncompliance does not stay any condition of this permit. [326 IAC 2-7-5(6)(C)] The notification by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) This permit shall be reopened and revised under any of the circumstances listed in IC 13-15-7-2 or if IDEM, OAQ, determines any of the following:

(1) That this permit contains a material mistake.

(2) That inaccurate statements were made in establishing the emissions standards or other terms or conditions.

(3) That this permit must be revised or revoked to assure compliance with an applicable requirement. [326 IAC 2-7-9(a)(3)]

(c) Proceedings by IDEM, OAQ, to reopen and revise this permit shall follow the same procedures as apply to initial permit issuance and shall affect only those parts of this permit for which cause to reopen exists. Such reopening and revision shall be made as expeditiously as practicable. [326 IAC 2-7-9(b)]

(d) The reopening and revision of this permit, under 326 IAC 2-7-9(a), shall not be initiated before notice of such intent is provided to the Permittee by IDEM, OAQ, at least thirty (30) days in advance of the date this permit is to be reopened, except that IDEM, OAQ, may provide a shorter time period in the case of an emergency. [326 IAC 2-7-9(c)]

B.17 Permit Renewal [326 IAC 2-7-4]

(a) The application for renewal shall be submitted using the application form or forms prescribed by IDEM, OAQ, and shall include the information specified in 326 IAC 2-7-4. Such information shall be included in the application for each emission unit at this source, except those emission units included on the trivial or insignificant activities list contained in 326 IAC 2-7-1(21) and 326 IAC 2-7-1(40). The renewal application does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Request for renewal shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

(b) Timely Submittal of Permit Renewal [326 IAC 2-7-4(a)(1)(D)]

(1) A timely renewal application is one that is:

(A) Submitted at least nine (9) months prior to the date of the expiration of this permit; and

(B) If the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

(2) If IDEM, OAQ, upon receiving a timely and complete permit application, fails to issue or deny the permit renewal prior to the expiration date of this permit, this existing permit shall not expire and all terms and conditions shall continue in effect, including any permit shield provided in 326 IAC 2-7-15, until the renewal permit has been issued or denied.

(c) Right to Operate After Application for Renewal [326 IAC 2-7-3]
If the Permittee submits a timely and complete application for renewal of this permit, the source's failure to have a permit is not a violation of 326 IAC 2-7 until IDEM, OAQ, takes final action on the renewal application, except that this protection shall cease to apply if, subsequent to the completeness determination, the Permittee fails to submit by the deadline specified in writing by IDEM, OAQ, any additional information identified as being needed to process the application.

(d) United States Environmental Protection Agency Authority [326 IAC 2-7-8(e)]
If IDEM, OAQ, fails to act in a timely way on a Part 70 permit renewal, the U.S. EPA may invoke its authority under Section 505(e) of the Clean Air Act to terminate or revoke and reissue a Part 70 permit.

B.18 Permit Amendment or Modification [326 IAC 2-7-11] [326 IAC 2-7-12]

(a) Permit amendments and modifications are governed by the requirements of 326 IAC 2-7-11 or 326 IAC 2-7-12 whenever the Permittee seeks to amend or modify this permit.

(b) Any application requesting an amendment or modification of this permit shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

Any such application shall be certified by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

B.19 Permit Revision Under Economic Incentives and Other Programs [326 IAC 2-7-5(8)] [326 IAC 2-7-12 (b)(2)]

(a) No Part 70 permit revision shall be required under any approved economic incentives, marketable Part 70 permits, emissions trading, and other similar programs or processes for changes that are provided for in a Part 70 permit.

(b) Notwithstanding 326 IAC 2-7-12(b)(1)(D)(i) and 326 IAC 2-7-12(c)(1), minor Part 70 permit modification procedures may be used for Part 70 modifications involving the use of economic incentives, marketable Part 70 permits, emissions trading, and other similar approaches to the extent that such minor Part 70 permit modification procedures are

explicitly provided for in the applicable State Implementation Plan (SIP) or in applicable requirements promulgated or approved by the U.S. EPA.

B.20 Operational Flexibility [326 IAC 2-7-20] [326 IAC 2-7-10.5]

(a) The Permittee may make any change or changes at the source that are described in 326 IAC 2-7-20(b), (c), or (e), without a prior permit revision, if each of the following conditions is met:

(1) The changes are not modifications under any provision of Title I of the Clean Air Act;

(2) Any preconstruction approval required by 326 IAC 2-7-10.5 has been obtained;

(3) The changes do not result in emissions which exceed the emissions allowable under this permit (whether expressed herein as a rate of emissions or in terms of total emissions);

(4) The Permittee notifies the:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Regulation Development Branch - Indiana (AR-18J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

in advance of the change by written notification at least ten (10) days in advance of the proposed change. The Permittee shall attach every such notice to the Permittee's copy of this permit; and

(5) The Permittee maintains records on-site which document, on a rolling five (5) year basis, all such changes and emissions trading that are subject to 326 IAC 2-7-20(b), (c), or (e) and makes such records available, upon reasonable request, for public review.

Such records shall consist of all information required to be submitted to IDEM, OAQ, in the notices specified in 326 IAC 2-7-20(b), (c)(1), and (e)(2).

(b) The Permittee may make Section 502(b)(10) of the Clean Air Act changes (this term is defined at 326 IAC 2-7-1(36)) without a permit revision, subject to the constraint of 326 IAC 2-7-20(a). For each such Section 502(b)(10) of the Clean Air Act change, the required written notification shall include the following:

(1) A brief description of the change within the source;

(2) The date on which the change will occur;

(3) Any change in emissions; and

(4) Any permit term or condition that is no longer applicable as a result of the change.

The notification which shall be submitted is not considered an application form, report or compliance certification. Therefore, the notification by the Permittee does not require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) Emission Trades [326 IAC 2-7-20(c)]
The Permittee may trade increases and decreases in emissions in the source, where the applicable SIP provides for such emission trades without requiring a permit revision, subject to the constraints of Section (a) of this condition and those in 326 IAC 2-7-20(c).

(d) Alternative Operating Scenarios [326 IAC 2-7-20(d)]
The Permittee may make changes at the source within the range of alternative operating scenarios that are described in the terms and conditions of this permit in accordance with 326 IAC 2-7-5(9). No prior notification of IDEM, OAQ, or U.S. EPA is required.

B.21 Source Modification Requirement [326 IAC 2-7-10.5]

A modification, construction, or reconstruction is governed by 326 IAC 2 and 326 IAC 2-7-10.5.

B.22 Inspection and Entry [326 IAC 2-7-6] [IC 13-14-2-2]

Upon presentation of proper identification cards, credentials, and other documents as may be required by law, and subject to the Permittee's right under all applicable laws and regulations to assert that the information collected by the agency is confidential and entitled to be treated as such, the Permittee shall allow IDEM, OAQ, U.S. EPA, or an authorized representative to perform the following:

(a) Enter upon the Permittee's premises where a Part 70 source is located, or emissions related activity is conducted, or where records must be kept under the conditions of this permit;

(b) Have access to and copy any records that must be kept under the conditions of this permit;

(c) Inspect any facilities, equipment (including monitoring and air pollution control equipment), practices, or operations regulated or required under this permit;

(d) Sample or monitor substances or parameters for the purpose of assuring compliance with this permit or applicable requirements; and

(e) Utilize any photographic, recording, testing, monitoring, or other equipment for the purpose of assuring compliance with this permit or applicable requirements.

B.23 Transfer of Ownership or Operational Control [326 IAC 2-7-11]

(a) The Permittee must comply with the requirements of 326 IAC 2-7-11 whenever the Permittee seeks to change the ownership or operational control of the source and no other change in the permit is necessary.

(b) Any application requesting a change in the ownership or operational control of the source shall contain a written agreement containing a specific date for transfer of permit responsibility, coverage and liability between the current and new Permittee. The application shall be submitted to:

Indiana Department of Environmental Management
Permits Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

The application which shall be submitted by the Permittee does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The Permittee may implement administrative amendment changes addressed in the request for an administrative amendment immediately upon submittal of the request. [326 IAC 2-7-11(c)(3)]

B.24 Annual Fee Payment [326 IAC 2-7-19] [326 IAC 2-7-5(7)]

(a) The Permittee shall pay annual fees to IDEM, OAQ, within thirty (30) calendar days of receipt of a billing. Pursuant to 326 IAC 2-7-19(b), if the Permittee does not receive a bill from IDEM, OAQ, the applicable fee is due April 1 of each year.

(b) Except as provided in 326 IAC 2-7-19(e), failure to pay may result in administrative enforcement action or revocation of this permit.

(c) The Permittee may call the following telephone numbers: 1-800-451-6027 or 317-233-0425 (ask for OAQ, Technical Support and Modeling Section), to determine the appropriate permit fee.

SECTION C SOURCE OPERATION CONDITIONS

Entire Source

Emission Limitations and Standards [326 IAC 2-7-5(1)]

C.1 Particulate Matter Emission Limitations For Processes with Process Weight Rates Less Than One Hundred (100) pounds per hour [326 IAC 6-3-2(c)]

Pursuant to 326 IAC 6-3-2(c), the allowable particulate matter emissions rate from any process not already regulated by 326 IAC 6-1 or any New Source Performance Standard, and which has a maximum process weight rate less than 100 pounds per hour shall not exceed 0.551 pounds per hour.

C.2 Opacity [326 IAC 5-1]

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) in any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

C.3 Open Burning [326 IAC 4-1] [IC 13-17-9]

The Permittee shall not open burn any material except as provided in 326 IAC 4-1-3, 326 IAC 4-1-4 or 326 IAC 4-1-6. The previous sentence notwithstanding, the Permittee may open burn in accordance with an open burning approval issued by the Commissioner under 326 IAC 4-1-4.1. 326 IAC 4-1-3 (a)(2)(A) and (B) are not federally enforceable.

C.4 Incineration [326 IAC 4-2] [326 IAC 9-1-2]

The Permittee shall not operate an incinerator or incinerate any waste or refuse except as provided in 326 IAC 4-2 and 326 IAC 9-1-2. 326 IAC 9-1-2 is not federally enforceable.

C.5 Fugitive Dust Emissions [326 IAC 6-4]

The Permittee shall not allow fugitive dust to escape beyond the property line or boundaries of the property, right-of-way, or easement on which the source is located, in a manner that would violate 326 IAC 6-4 (Fugitive Dust Emissions). 326 IAC 6-4-2(4) is not federally enforceable.

C.6 Operation of Equipment [326 IAC 2-7-6(6)]

Except as otherwise provided by statute or rule, or in this permit, all air pollution control equipment listed in this permit and used to comply with an applicable requirement shall be operated at all times that the emission units vented to the control equipment are in operation.

C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

(a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.

(b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work

or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:

(1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or

(2) If there is a change in the following:

(A) Asbestos removal or demolition start date;

(B) Removal or demolition contractor; or

(C) Waste disposal site.

(c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).

(d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Asbestos Section, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana Licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(e) Procedures for Asbestos Emission Control
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-4, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.

(f) Indiana Accredited Asbestos Inspector
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Accredited Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos. The requirement that the inspector be accredited, pursuant to the provisions of 40 CFR 61, Subpart M, is federally enforceable.

Testing Requirements [326 IAC 2-7-6(1)]

C.8 Performance Testing [326 IAC 3-6]

(a) All testing shall be performed according to the provisions of 326 IAC 3-6 (Source Sampling Procedures), except as provided elsewhere in this permit, utilizing any applicable procedures and analysis methods specified in 40 CFR 51, 40 CFR 60, 40 CFR 61, 40 CFR 63, 40 CFR 75, or other procedures approved by IDEM, OAQ.

A test protocol, except as provided elsewhere in this permit, shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

no later than thirty-five (35) days prior to the intended test date. The protocol submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The Permittee shall notify IDEM, OAQ of the actual test date at least fourteen (14) days prior to the actual test date. The notification submitted by the Permittee does not require certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) Pursuant to 326 IAC 3-6-4(b), all test reports must be received by IDEM, OAQ not later than forty-five (45) days after the completion of the testing. An extension may be granted by IDEM, OAQ, if the source submits to IDEM, OAQ, a reasonable written explanation not later than five (5) days prior to the end of the initial forty-five (45) day period.

Compliance Requirements [326 IAC 2-1.1-11]

C.9 Compliance Requirements [326 IAC 2-1.1-11]

The commissioner may require stack testing, monitoring, or reporting at any time to assure compliance with all applicable requirements. Any monitoring or testing shall be performed in accordance with 326 IAC 3 or other methods approved by the commissioner or the U. S. EPA.

Compliance Monitoring Requirements [326 IAC 2-7-5(1)] [326 IAC 2-7-6(1)]

C.10 Compliance Monitoring [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

Unless otherwise specified in this permit, all monitoring and record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance. If required by Section D, the Permittee shall be responsible for installing any necessary equipment and initiating any required monitoring related to that equipment. If due to circumstances beyond its control, that equipment cannot be installed and operated within ninety (90) days, the Permittee may extend the compliance schedule related to the equipment for an additional ninety (90) days provided the Permittee notifies:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

in writing, prior to the end of the initial ninety (90) day compliance schedule, with full justification of the reasons for the inability to meet this date.

The notification which shall be submitted by the Permittee does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

Unless otherwise specified in the approval for the new emission unit(s), compliance monitoring for new emission units or emission units added through a source modification shall be implemented when operation begins.

C.11 Monitoring Methods [326 IAC 3] [40 CFR 60] [40 CFR 63]

Any monitoring or testing required by Section D of this permit shall be performed according to the provisions of 326 IAC 3, 40 CFR 60, Appendix A, 40 CFR 60 Appendix B, 40 CFR 63, or other approved methods as specified in this permit.

C.12 Pressure Gauge and Other Instrument Specifications [326 IAC 2-1.1-11] [326 IAC 2-7-5(3)] [326 IAC 2-7-6(1)]

(a) Whenever a condition in this permit requires the measurement of pressure drop across any part of the unit or its control device, the gauge employed shall have a scale such that the expected normal reading shall be no less than twenty percent (20%) of full scale and be accurate within plus or minus two percent (±2%) of full scale reading.

(b) The Permittee may request the IDEM, OAQ approve the use of a pressure gauge or other instrument that does not meet the above specifications provided the Permittee can demonstrate an alternative pressure gauge or other instrument specification will adequately ensure compliance with permit conditions requiring the measurement of pressure drop or other parameters.

Corrective Actions and Response Steps [326 IAC 2-7-5] [326 IAC 2-7-6]

C.13 Emergency Reduction Plans [326 IAC 1-5-2] [326 IAC 1-5-3]

Pursuant to 326 IAC 1-5-2 (Emergency Reduction Plans; Submission):

(a) The Permittee shall prepare written emergency reduction plans (ERPs) consistent with safe operating procedures.

(b) These ERPs shall be submitted for approval to:

Indiana Department of Environmental Management
Compliance Branch, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

within ninety (90) days after the date of issuance of this permit.

The ERP does require the certification by the “responsible official” as defined by 326 IAC 2-7-1(34).

(c) If the ERP is disapproved by IDEM, OAQ, the Permittee shall have an additional thirty (30) days to resolve the differences and submit an approvable ERP.

(d) These ERPs shall state those actions that will be taken, when each episode level is declared, to reduce or eliminate emissions of the appropriate air pollutants.

(e) Said ERPs shall also identify the sources of air pollutants, the approximate amount of reduction of the pollutants, and a brief description of the manner in which the reduction will be achieved.

(f) Upon direct notification by IDEM, OAQ, that a specific air pollution episode level is in effect, the Permittee shall immediately put into effect the actions stipulated in the approved ERP for the appropriate episode level. [326 IAC 1-5-3]

C.14 Risk Management Plan [326 IAC 2-7-5(12)] [40 CFR 68.215]

If a regulated substance, subject to 40 CFR 68, is present at a source in more than a threshold quantity, 40 CFR 68 is an applicable requirement and the Permittee shall submit:

(a) A compliance schedule for meeting the requirements of 40 CFR 68; or

(b) As a part of the annual compliance certification submitted under 326 IAC 2-7-6(5), a certification statement that the source is in compliance with all the requirements of 40 CFR 68, including the registration and submission of a Risk Management Plan (RMP);

All documents submitted pursuant to this condition shall include the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

C.15 Compliance Response Plan - Preparation, Implementation, Records, and Reports [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) The Permittee is required to prepare a Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. A CRP shall be submitted to IDEM, OAQ upon request. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee, supplemented from time to time by the Permittee, maintained on site, and comprised of:

(1) Reasonable response steps that may be implemented in the event that a response step is needed pursuant to the requirements of Section D of this permit; and an expected timeframe for taking reasonable response steps.

(2) If, at any time, the Permittee takes reasonable response steps that are not set forth in the Permittee's current Compliance Response Plan and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan to include such response steps taken.

(b) For each compliance monitoring condition of this permit, reasonable response steps shall be taken when indicated by the provisions of that compliance monitoring condition as follows:

(1) Reasonable response steps shall be taken as set forth in the Permittee's current Compliance Response Plan; or

(2) If none of the reasonable response steps listed in the Compliance Response Plan is applicable or responsive to the excursion, the Permittee shall devise and implement additional response steps as expeditiously as practical. Taking such additional response steps shall not be considered a deviation from this permit so long as the Permittee documents such response steps in accordance with this condition.

(3) If the Permittee determines that additional response steps would necessitate that the emissions unit or control device be shut down, the IDEM, OAQ shall be promptly notified of the expected date of the shut down, the status of the applicable compliance monitoring parameter with respect to normal, and the results of the actions taken up to the time of notification.

(4) Failure to take reasonable response steps shall constitute a violation of the permit.

(c) The Permittee is not required to take any further response steps for any of the following reasons:

(1) A false reading occurs due to the malfunction of the monitoring equipment and prompt action was taken to correct the monitoring equipment.

(2) The Permittee has determined that the compliance monitoring parameters established in the permit conditions are technically inappropriate, has previously submitted a request for a minor permit modification to the permit, and such request has not been denied.

(3) An automatic measurement was taken when the process was not operating.

(4) The process has already returned or is returning to operating within "normal" parameters and no response steps are required.

(d) When implementing reasonable steps in response to a compliance monitoring condition, if the Permittee determines that an exceedance of an emission limitation has occurred, the Permittee shall report such deviations pursuant to Section B-Deviations from Permit Requirements and Conditions.

(e) The Permittee shall record all instances when response steps are taken. In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

(f) Except as otherwise provided by a rule or provided specifically in Section D, all monitoring as required in Section D shall be performed when the emission unit is operating, except for time necessary to perform quality assurance and maintenance activities.

C.16 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall take appropriate response actions. The Permittee shall submit a description of these response actions to IDEM, OAQ, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize excess emissions from the affected facility while the response actions are being implemented.

(b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAQ that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAQ may extend the retesting deadline.

(c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The documents submitted pursuant to this condition do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

C.17 Emission Statement [326 IAC 2-7-5(3)(C)(iii)] [326 IAC 2-7-5(7)] [326 IAC 2-7-19(c)] [326 IAC 2-6]

(a) The Permittee shall submit an annual emission statement certified pursuant to the requirements of 326 IAC 2-6, that must be received by July 1 of each year and must comply with the minimum requirements specified in 326 IAC 2-6-4. The annual emission statement shall meet the following requirements:

(1) Indicate estimated actual emissions of criteria pollutants from the source, in compliance with 326 IAC 2-6 (Emission Reporting);

(2) Indicate estimated actual emissions of other regulated pollutants (as defined by 326 IAC 2-7-1) from the source, for purposes of Part 70 fee assessment.

(b) The annual emission statement covers the twelve (12) consecutive month time period starting January 1 and ending December 31. The annual emission statement must be submitted to:

Indiana Department of Environmental Management
Technical Support and Modeling Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

The emission statement does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(c) The annual emission statement required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

C.18 General Record Keeping Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-6]

(a) Records of all required data, reports and support information shall be retained for a period of at least five (5) years from the date of monitoring sample, measurement, report, or application. These records shall be kept at the source location for a minimum of three (3) years. The records may be stored elsewhere for the remaining two (2) years as long as they are available upon request. If the Commissioner makes a request for records to the Permittee, the Permittee shall furnish the records to the Commissioner within a reasonable time.

(b) Unless otherwise specified in this permit, all record keeping requirements not already legally required shall be implemented within ninety (90) days of permit issuance.

C.19 General Reporting Requirements [326 IAC 2-7-5(3)(C)] [326 IAC 2-1.1-11]

(a) The source shall submit the attached Quarterly Deviation and Compliance Monitoring Report or its equivalent. Any deviation from permit requirements, the date(s) of each deviation, the cause of the deviation, and the response steps taken must be reported. This report shall be submitted within thirty (30) days of the end of the reporting period. The Quarterly Deviation and Compliance Monitoring Report shall include the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) The report required in (a) of this condition and reports required by conditions in Section D of this permit shall be submitted to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

(c) Unless otherwise specified in this permit, any notice, report, or other submission required by this permit shall be considered timely if the date postmarked on the envelope or certified mail receipt, or affixed by the shipper on the private shipping receipt, is on or before the date it is due. If the document is submitted by any other means, it shall be considered timely if received by IDEM, OAQ, on or before the date it is due.

(d) Unless otherwise specified in this permit, all reports required in Section D of this permit shall be submitted within thirty (30) days of the end of the reporting period. All reports do require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(e) The first report shall cover the period commencing on the date of issuance of this permit and ending on the last day of the reporting period. Reporting periods are based on calendar years.

Stratospheric Ozone Protection

C.20 Compliance with 40 CFR 82 and 326 IAC 22-1

Pursuant to 40 CFR 82 (Protection of Stratospheric Ozone), Subpart F, except as provided for motor vehicle air conditioners in Subpart B, the Permittee shall comply with the standards for recycling and emissions reduction:

(a) Persons opening appliances for maintenance, service, repair, or disposal must comply with the required practices pursuant to 40 CFR 82.156.

(b) Equipment used during the maintenance, service, repair, or disposal of appliances must comply with the standards for recycling and recovery equipment pursuant to 40 CFR 82.158.

(c) Persons performing maintenance, service, repair, or disposal of appliances must be certified by an approved technician certification program pursuant to 40 CFR 82.161.

SECTION D.1 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

(a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.1.1 Particulate Matter Limitation (PM) [326 IAC 6-2-4]

Pursuant to 326 IAC 6-2-4 (Particulate Matter Emission Limitations for Sources of Indirect Heating), the PM emissions from each 20.9 MMBtu per hour heat input boiler shall be limited to 0.4 pounds per MMBtu heat input.

This limitation is based on the following equation:

$$P_t = \frac{1.09}{Q^{0.26}}$$

Where: P_t = Pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input; and

Q = Total source maximum operating capacity rating in million Btu per hour (MMBtu/hr) heat input (Includes the two (2) 20.9 MMBtu/hr boilers, and the insignificant boilers: 3.6 MMBtu/hr boiler and 4.8 MMBtu/hr boiler.

D.1.2 Particulate Matter Limitation [326 IAC 12-1] [40 CFR 60, Subpart Dc]

Although this boiler is subject to 40 CFR 60, Subpart Dc (Standards of Performance for Small Industrial - Commercial - Institutional Steam Generating Units), there are no emission limitations applicable to this boiler, only record keeping requirements described in D.1.4.

D.1.3 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for this facility.

Record Keeping and Reporting Requirements [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.1.4 Record Keeping Requirements [326 IAC 12-1] [40 CFR 60, Subpart Dc]

(a) To document compliance with Condition D.1.2, the Permittee shall maintain records in accordance with (1) through (2) below.

(1) Calendar dates covered in the compliance determination period; and

(2) Monthly fuel records.

The Permittee shall retain records of all recording/monitoring data and support information for a period of five (5) years, or longer if specified elsewhere in this permit, from the date of the monitoring sample, measurement, or report. Support information includes all calibration and maintenance records and all original strip-chart recordings for continuous monitoring instrumentation, and copies of all reports required by this permit.

(b) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.1.5 Reporting Requirements

(a) A certification, signed by the responsible official, that certifies all of the fuels combusted during the period. The natural gas-fired boiler certification does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34);

(b) The natural gas boiler certification shall be submitted to the address listed in Section C - General Reporting Requirements, of this permit, using the reporting forms located at the end of this permit, or their equivalent, within thirty (30) days after the end of the six (6) month period being reported.

SECTION D.2 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

(b) One (1) tablet manufacturing department, constructed in 1993, consisting of

(1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) electric production ovens, equipped with a baghouse for particulate matter control, identified as V2.

(2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with a baghouse for particulate matter control, identified as V4.

(3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate mater control, identified as V6 and V9.

(c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.

(d) One (1) Phase IIIA production area, identified as emission unit 02 (EU-02). This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse EU-02. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. The production area includes one (1) flo-coater for the application of sustained release coating, equipped with two (2) baghouses, identified as V7 and V8. These units were constructed in 2000.

(e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.2.1 Particulate Matter (PM) [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the tablet, capsule and phase IIIA manufacturing facilities shall not exceed the following PM emission limits:

Facility	Process Weight	PM Emission Limit (lbs/hour)
Tablet Manufacturing Department	26	0.23
Capsule Manufacturing Department	13.8	0.14
Phase IIIA Production Area	8.8	0.11

The pounds per hour limitation was calculated using the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

D.2.2 Organic Solvents [326 IAC 8-1-6]

Pursuant to 326 IAC 8-1-6, the Best Available Control Technology (BACT) for the Control of volatile organic compounds shall be implemented and is as follows:

(a) Process Modifications:

(1) For capsule manufacturing, the Permittee shall use flo-coaters for applying sustained release coatings for all products in which volatile organic compounds (VOCs) are used.

(2) The capture and offsite disposal of VOC containing chemicals; and

(3) Solvent handing procedures (currently being conducted):

(A) Solvents are stored in sealed 55-gallon drums until utilized in the manufacturing process.

(B) The drums are kept sealed except where solvents are withdrawn.

(C) The solvents are extracted from the drums using a dedicated pump.

(D) If one half of the drum content is needed, the entire drum can be transported to the manufacturing area for dispensing.

(E) If less than one half of the content of the drum is to be used, the needed portion is transported to the process area in a covered container.

(F) Where the manufacturing process requires other chemicals to be dissolved in liquid, the process is conducted in covered vessels.

(G) The use of isopropanol in cleaning and sanitizing operations shall be minimized by using bleaches and other non-solvent sanitizers where appropriate.

(4) The BACT shall be implemented such that:

(A) Implementation of the flo-coater shall reduce VOC emissions by 18%.

(B) The solvents shall be disposed offsite in accordance with the applicable hazardous waste rule found in 60 CFR Part 260 to Part 272, and shall reduce VOC emissions by 8%.

(C) The on-going solvent handling procedures shall reduce VOC emissions by 0.5%.

(D) The minimization of isopropanol in cleaning and sanitizing operations shall reduce VOC emissions by 8%.

The implementation of this BACT shall result in a total VOC reduction of 34.5% from 1995 VOC emission levels.

(b) Condition 4 in CP 071-2389-00023, issued on February 3, 1993, has been superseded by the requirements specified in Condition D.2.2(a) of this permit.

(c) Condition 6(a)(2) in CP 071-3874-00023, issued on January 25, 1995, has been superseded by the requirements specified in Condition D.2.2(a)(1) of this permit.

(d) Condition 6(a)(1) in CP 071-3874-00023, issued on January 25, 1995, has been superseded by the requirements specified in Condition D.2.2(a)(3)(G) of this permit.

D.2.3 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

Pursuant to 40 CFR 63.1251 (National Emission Standards for Pharmaceuticals Production), the source is subject to 40 CFR 63, Subpart GGG, however no control requirements apply because the source does not have any emission vents regulated by the rule. All vents have HAP concentrations in their vent stream less than 50 ppmv. Therefore, these vents are not considered “process vents” by the rule and are not regulated. Any changes to the process that would increase emissions from any individual vent to greater than 50 ppmv requires prior approval from IDEM, OAQ.

D.2.4 General Provisions Relating to NESHAPs [326 IAC 20-1] [40 CFR 63, Subpart A]

The provisions of 40 CFR 63, Subpart A - General Provisions, which are incorporated by reference in 326 IAC 20-1, apply to the facilities and operations described in this section except when otherwise specified in 40 CFR 63, Subpart GGG.

D.2.5 Preventive Maintenance Plan [326 IAC 2-7-5(13)]

A Preventive Maintenance Plan, in accordance with Section B - Preventive Maintenance Plan, of this permit, is required for these facilities and their control devices.

Compliance Determination Requirements

D.2.6 Particulate Matter (PM)

Pursuant to CP-071-238-00023, issued on February 3, 1993,CP071-3874-00023, issued on January 25, 1995, and Minor Source Modification 071-11653-00023, issued on April 20, 2000, and in order to comply with Condition D.2.1 the baghouses V2, V4, V5, V6, V7, V8, V9, and EU-2 for PM control shall be in operation and control emissions from the tablet, capsule, and Phase IIIA manufacturing facilities at all times these facilities are in operation.

D.2.7 National Emission Standards for Pharmaceuticals Production [326 IAC 20-1][40 CFR 63, Subpart GGG]

Pursuant to 40 CFR 63, Subpart GGG (National Emission Standards for Pharmaceuticals Production), HAP emissions from individual vents shall be determined using one of the following methods:

(a) Process knowledge that indicates no HAP are present in the emission stream

(b) Testing using Methods 18 of 40 CFR 63, Appendix A;

(c) Testing using test methods validated according to the procedures in Method 301 of 40 CFR 60, of Appendix A; or

(d) Engineering assessments as described in 40 CFR 63.1257(d)(2)(ii), which includes by is not limited to:

(1) Previous test results, provided the tests are representative of current operating practices at the facility.

(2) Bench-scale or pilot test data representative of the process under representative operating conditions.

(3) Maximum flow rate, HAP emission rate, concentration, or other relevant parameter specified or implied within a permit limit applicable to the process vent.

(4) Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:

(i) Use of material balances based on process stoichiometry to estimate maximum organic HAP concentrations.

(ii) Estimation of maximum flow rate based on physical equipment design such as pump or blower capacities.

(iii) Estimation of HAP concentrations based on saturation conditions.

(5) All data, assumptions, and procedures used in the engineering assessment shall be documented in accordance with 40 CFR 63.1260(e). Data or other information supporting a finding that the emissions estimation equations are inappropriate shall be reported in the precompliance report.

Compliance Monitoring Requirements [326 IAC 2-7-6(1)] [326 IAC 2-7-5(1)]

D.2.8 Visible Emissions Notations

(a) Visible emission notations of the tablet, capsule and Phase IIIA manufacturing facility exhausts shall be performed once per shift during normal daylight operations when exhausting to the atmosphere. A trained employee shall record whether emissions are normal or abnormal.

(b) For processes operated continuously, "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time.

(c) In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions.

(d) A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process.

(e) The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when an abnormal emission is observed. Failure to take response steps in accordance with Section C - Compliance Monitoring Plan - Failure to Take Response Steps, shall be considered a violation of this permit.

D.2.9 Parametric Monitoring

The Permittee shall record the total static pressure drop across the baghouses V2, V4, V5, V6, V7, V8, V9 and EU-2 used in conjunction with the tablet, capsule, and phase IIIA manufacturing facilities, at least once per shift when these facilities are in operation when venting to the atmosphere. When for any one reading, the pressure drop across the baghouses (V2, V4, V5, V6, V7, V8, V9, and EU-2) is outside the range of 3.0 and 6.0 inches of water or a range established during the latest stack test the Permittee shall take reasonable response steps in accordance with Section C - Compliance Response Plan. A pressure reading that is outside the above mentioned range is not a deviation from this permit. Failure to take response steps in

accordance with Section C - Compliance Response Plan - Preparation, Implementation, Records, and Reports, shall be considered a violation of this permit.

The instrument used for determining the pressure shall comply with Section C - Pressure Gauge and Other Instruments Specifications, of this permit, shall be subject to approval by IDEM, OAQ, and shall be calibrated at least once every six (6) months.

D.2.10 Baghouse Inspections

An inspection shall be performed each calender quarter of all bags controlling the tablet, capsule, and phase IIIA manufacturing facilities when venting to the atmosphere. A baghouse inspection shall be performed within three months of redirecting vents to the atmosphere and every three months thereafter. Inspections are optional when venting to the indoors. All defective bags shall be replaced.

D.2.11 Broken or Failed Bag Detection

In the event that bag failure has been observed:

(a) The affected compartments will be shut down immediately until the failed units have been repaired or replaced. Within eight (8) hours of the determination of failure, response steps according to the timetable described in the Compliance Response Plan shall be initiated. For any failure with corresponding response steps and timetable not described in the Compliance Response Plan, response steps shall be devised within eight (8) hours of discovery of the failure and shall include a timetable for completion. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

(b) For single compartment baghouses, failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

Record Keeping and Reporting Requirement [326 IAC 2-7-5(3)] [326 IAC 2-7-19]

D.2.12 Record Keeping Requirements

(a) To document compliance with Condition D.2.8, the Permittee shall maintain records of visible emission notations of the tablet, capsule and phase IIIA manufacturing facilities stack exhaust once per shift.

(b) To document compliance with Condition D.2.9, the Permittee shall maintain the following:

(1) Once per shift records of the following operational parameters during normal operation when venting to the atmosphere:

(A) Inlet and outlet differential static pressure; and

(B) Cleaning cycle operation.

(2) Documentation of the dates vents are redirected.

(c) To document compliance with Condition D.2.10, the Permittee shall maintain records of the results of the inspections required under Condition D.2.10 and the dates the vents are redirected.

(d) To document compliance with Condition D.2.2, the Permittee shall maintain monthly logs of information pertaining to the usage and handling of volatile organic solvents and the implementation of the flo-coaters.

(e) To document compliance with Condition D.2.3 and D.2.7, the permittee shall keep records showing the HAP concentrations of all vent streams and the information necessary to support how the HAP concentrations were determined.

(f) All records shall be maintained in accordance with Section C - General Record Keeping Requirements, of this permit.

D.2.13 Record Keeping Requirements for 40 CFR 63, Subpart GGG

Pursuant to 40 CFR 63, Subpart A and 40 CFR 63, Subpart GGG, the Permittee shall maintain the following records:

(a) Copies of all records and reports required by 40 CFR 63, Subpart GGG.

(b) Copies of the current and superceded versions of the Startup, Shutdown, and Malfunction plan.

(c) Copies of startup, shutdown and malfunction records required under 40 CFR 63, Subpart GGG.

D.2.14 Reporting Requirements for 40 CFR 63, Subpart GGG

(a) Pursuant to 40 CFR 63, Subpart A, the Permittee shall submit an initial notification to the Administrator immediately upon issuance of this permit. The initial notification shall contain:

(1) The name and address of the owner or operator;

(2) The address (i.e., physical location) of the emission units;

(3) An identification of the relevant standard, or other requirement, that is the basis of the notification and the date on which the source is required to be in compliance; and

(4) A statement indicating whether the source is a major source or an area source.

(b) Pursuant to 40 CFR 63, Subpart GGG, the Permittee shall submit a Precompliance report at least 6 months prior to September 21, 2001. The Administrator shall have 90 days to approve or disapprove the plan. The plan shall be considered approved if the Administrator either approves or disapproves the plan in writing or fails to disapprove the plan in writing. If the request is denied, the Permittee must still be in compliance with the standard by the compliance date. The Precompliance report shall data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in 40 CFR 63.1257(d)(2)(ii).

(c) Pursuant to 40 CFR 63.9, the Permittee shall submit a Notification of Compliance Status Report no later than 150 days after the compliance date. This report shall include:

(1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.

(2) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.

(3) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.

(4) Listing of all operating scenarios.

(5) Description of worst-case operating and /or testing conditions for control devices.

(6) Identification of emission points subject to overlapping requirements described in 40 CFR 63.1250(h) and the authority under which the Permittee will comply.

(d) Pursuant to 40 CFR 63.1260(g), the Permittee shall submit Periodic Reports semiannually, beginning 60 operating days after the end of the applicable reporting period. The first report shall be submitted no later than 240 days after the date of Notification of Compliance Status is due and shall cover the 6-month period beginning on the date of Notification of Compliance Status is due.

(e) Pursuant to 40 CFR 63.1260(h), the Permittee shall submit a quarterly report whenever a process change is made or a change in any of the information submitted in the Notification of Compliance Status Report. The report may by submitted as part of the next Periodic report required under 40 CFR 63.1260(g). The report shall include:

(1) A brief description of the process change.

(2) A description of any modifications to the standard procedures or quality assurance procedures.

(3) Revisions to any of the information reported in the original Notification of Compliance Status Report.

(4) Information required by the Notification of Compliance Report under 40 CFR 63.1260(f).

SECTION D.3 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]:

(f) One (1) Colyte production area (identified as emission unit 01 (EU-01)), used manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse EU-01.

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.3.1 Particulate Matter (PM) [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the colyte manufacturing department shall not exceed 0.187 pounds per hour when operating at a process weight rate of 20 pounds per hour. The pounds per hour limitation was calculated using the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

Compliance Determination Requirements

D.3.2 Particulate Matter (PM)

Pursuant to Minor Source Modification CP-071-11653-00023, issued on April 20, 2000, and in order to comply with D.3.1, the baghouse EU-1 for PM control shall be in operation and control emissions from the colyte manufacturing facility at all times that the colyte manufacturing facility is in operation.

SECTION D.4 FACILITY OPERATION CONDITIONS

Facility Description [326 IAC 2-7-5(15)]: Insignificant Activities

(a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed between 1985 and 2000, including:

(1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4];

(2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4]; and

(b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment [326 IAC 6-3].

(c) Paved and unpaved roads and parking lots with public access [326 IAC 6-4].

(d) Other categories with emissions below insignificant thresholds:

(1) A liquid pharmaceutical manufacturing facility, consisting of liquid blending, filtration, and packaging, emitting less than three (3) pounds per hour of VOC.

(2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as V1. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

(The information describing the process contained in this facility description box is descriptive information and does not constitute enforceable conditions.)

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.4.1 Particulate Matter (PM)

(a) Pursuant to 326 IAC 6-2-4 (Emission Limitations for facilities specified in 326 IAC 6-2-1(d)), the particulate emissions from the 3.6 MMBtu/hour and 4.8 MMBtu/hour boilers shall be limited to 0.6 pounds per MMBtu heat input.

This limitation is based on the following equation:

$$P_t = \frac{1.09}{Q^{0.26}}$$

Where: P_t = Pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input; and

Q = Total source maximum operating capacity rating in million Btu per hour (MMBtu/hr) heat input (Includes the 4.8 MMBtu/hr boiler, and the 3.6 MMBtu/hr boiler).

Emission Limitations and Standards [326 IAC 2-7-5(1)]

D.4.2 Particulate Matter (PM) [326 IAC 6-3-2]

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the product weigh-up department and welding equipment shall not exceed the allowable PM emission rate based on the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

PART 70 OPERATING PERMIT
CERTIFICATION

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

This certification shall be included when submitting monitoring, testing reports/results or other documents as required by this permit.

Please check what document is being certified:

9 Annual Compliance Certification Letter

9 Test Result (specify) _____

9 Report (specify) _____

9 Notification (specify) _____

9 Affidavit (specify) _____

9 Other (specify) _____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete.

Signature:

Printed Name:

Title/Position:

Phone:

Date:

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY

COMPLIANCE BRANCH
100 North Senate Avenue
P.O. Box 6015
Indianapolis, Indiana 46206-6015
Phone: 317-233-5674
Fax: 317-233-5967

PART 70 OPERATING PERMIT
EMERGENCY OCCURRENCE REPORT

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

This form consists of 2 pages **Page 1 of 2**

9 This is an emergency as defined in 326 IAC 2-7-1(12)

- The Permittee must notify the Office of Air Quality (OAQ), within four (**4**) business hours (1-800-451-6027 or 317-233-5674, ask for Compliance Section); and
- The Permittee must submit notice in writing or by facsimile within two (**2**) days (Facsimile Number: 317-233-5967), and follow the other requirements of 326 IAC 2-7-16.

If any of the following are not applicable, mark N/A

Facility/Equipment/Operation:
Control Equipment:
Permit Condition or Operation Limitation in Permit:
Description of the Emergency:
Describe the cause of the Emergency:

If any of the following are not applicable, mark N/A **Page 2 of 2**

Date/Time Emergency started:
Date/Time Emergency was corrected:
Was the facility being properly operated at the time of the emergency? Y N Describe:
Type of Pollutants Emitted: TSP, PM-10, SO_2, VOC, NO_X, CO, Pb, other:
Estimated amount of pollutant(s) emitted during emergency:
Describe the steps taken to mitigate the problem:
Describe the corrective actions/response steps taken:
Describe the measures taken to minimize emissions:
If applicable, describe the reasons why continued operation of the facilities are necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value:

Form Completed by: _____

Title / Position: _____

Date: _____

Phone: _____

A certification is not required for this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION

PART 70 OPERATING PERMIT
SEMI-ANNUAL NATURAL GAS FIRED BOILER CERTIFICATION

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

9	Natural Gas Only
9	Alternate Fuel burned From:_____ To:_____

I certify that, based on information and belief formed after reasonable inquiry, the statements and information in the document are true, accurate, and complete. Signature:
Printed Name:
Title/Position:
Phone:
Date:

A certification by the responsible official as defined by 326 IAC 2-7-1(34) is required for this report.

INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT
OFFICE OF AIR QUALITY
COMPLIANCE DATA SECTION

PART 70 OPERATING PERMIT
QUARTERLY DEVIATION AND COMPLIANCE MONITORING REPORT

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Address: 1101 C Avenue West, Seymour, Indiana 47274
Mailing Address: 1101 C Avenue West, Seymour, Indiana 47274
Part 70 Permit No.: 071-7162-00023

Months: _____ **to** _____ **Year:** _____

This report is an affirmation that the source has met all the requirements stated in this permit. This report shall be submitted quarterly based on a calendar year. Any deviation from the requirements, the date(s) of each deviation, the probable cause of the deviation, and the response steps taken must be reported. Deviations that are required to be reported by an applicable requirement shall be reported according to the schedule stated in the applicable requirement and do not need to be included in this report. Additional pages may be attached if necessary. If no deviations occurred, please specify in the box marked "No deviations occurred this reporting period".

9 NO DEVIATIONS OCCURRED THIS REPORTING PERIOD.

9 THE FOLLOWING DEVIATIONS OCCURRED THIS REPORTING PERIOD

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Page 2 of 2

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Permit Requirement (specify permit condition #)	
Date of Deviation:	**Duration of Deviation:**
Number of Deviations:	
Probable Cause of Deviation:	
Response Steps Taken:	

Form Completed By: ______________________________

Title/Position: ______________________________

Date: ______________________________

Phone: ______________________________

Attach a signed certification to complete this report.

March 25, 2002

Indiana Department of Environmental Management
Office of Air Quality

Addendum to the Technical Support Document
for A Part 70 Operating Permit

Source Background and Description

Source Name:	Schwarz Pharma Manufacturing, Inc.
Source Location:	1101 C Avenue West, Seymour, Indiana 47274
County:	Jackson
SIC Code:	2834
Operation Permit No.:	TO71-7162-00023
Permit Reviewer:	ERG/AB

On October 4, 2001, the Office of Air Quality (OAQ) had a notice published in The Tribune, Seymour, Indiana, stating that Schwarz Pharma Manufacturing, Inc. had applied for a Part 70 Operating Permit to operate a batch pharmaceutical manufacturing facility producing liquid, capsule, and tablet pharmaceuticals. The notice also stated that OAQ proposed to issue a permit for this operation and provided information on how the public could review the proposed permit and other documentation. Finally, the notice informed interested parties that there was a period of thirty (30) days to provide comments on whether or not this permit should be issued as proposed.

Upon further review, the OAQ decided to make the following revisions to the permit (bolded language has been added, the language with a line through it has been deleted). The Table Of Contents has been modified to reflect these changes.

1. Condition B.10 on page 8 has been revised to indicate that the Annual Compliance Certification should be submitted to the Compliance Branch and not to the Compliance Data Section as indicated in the draft permit.

2. The words “Compliance Branch” have been deleted from the Part 70 Operating Permit Certification Form on page 38 of the draft permit.

3. The Semi-annual Natural-Gas Fired Boiler Certification Form has been revised to indicate that this form should be submitted to the Compliance Data Section and not to the Compliance Branch as indicated on the draft permit. In addition, the reference to “Alternate Fuel Burned” has been deleted from the Semi-Annual Natural Gas Fired Boiler Certification Form, because the boilers in question fire only on natural gas.

4. The Quarterly Deviation and Compliance Monitoring Report Form has been revised to indicate that this form should be submitted to the Compliance Data Section and not to the Compliance Branch as indicated on the draft permit.

B.10 Annual Compliance Certification [326 IAC 2-7-6(5)]

(a) The Permittee shall annually submit a compliance certification report which addresses the status of the source’s compliance with the terms and conditions contained in this permit, including emission limitations, standards, or work practices. The initial certification shall cover the time period from the date of final permit issuance through December 31 of the same year. All subsequent certifications shall cover the time period

from January 1 to December 31 of the previous year, and shall be submitted in letter form no later than July 1 of each year to:

Indiana Department of Environmental Management
Compliance **Branch** ~~Data Section~~, Office of Air Quality
100 North Senate Avenue, P. O. Box 6015
Indianapolis, Indiana 46206-6015

and

United States Environmental Protection Agency, Region V
Air and Radiation Division, Air Enforcement Branch - Indiana (AE-17J)
77 West Jackson Boulevard
Chicago, Illinois 60604-3590

5. The citation for the new rule 326 IAC 2-1.1-9.5 has been added to Condition B.2 Permit Term.

B.2 Permit Term [326 IAC 2-7-5(2)] **[326 IAC 2-1.1-9.5]**

This permit is issued for a fixed term of five (5) years from the original date, as determined in accordance with IC 4-21.5-3-5(f) and IC 13-15-5-3. Subsequent revisions, modifications, or amendments of this permit do not affect the expiration date.

6. B.12 Emergency Provisions (a)(b) and (g) have been revised to reflect rule changes to 326 IAC 2-7-16.

B.12 Emergency Provisions [326 IAC 2-7-16]

(a) An emergency, as defined in 326 IAC 2-7-1(12), is not an affirmative defense for an action brought for noncompliance with a federal or state health-based emission limitation~~, except as provided in 326 IAC 2-7-16.~~

(b) An emergency, as defined in 326 IAC 2-7-1(12), constitutes an affirmative defense to an action brought for noncompliance with a ~~health-based or~~ technology-based emission limitation if the affirmative defense of an emergency is demonstrated through properly signed, contemporaneous operating logs or other relevant evidence that describe the following:

(g) ~~Operations may continue during an emergency only if the following conditions are met~~:

~~(1)~~ If the emergency situation causes a deviation from a technology-based limit, the Permittee may continue to operate the affected emitting facilities during the emergency provided the Permittee immediately takes all reasonable steps to correct the emergency and minimize emissions.

~~(2) If an emergency situation causes a deviation from a health-based limit, the Permittee may not continue to operate the affected emissions facilities unless:~~

~~(A) The Permittee immediately takes all reasonable steps to correct the emergency situation and to minimize emissions; and~~

~~(B) Continued operation of the facilities is necessary to prevent imminent injury to persons, severe damage to equipment, substantial loss of capital investment, or loss of product or raw materials of substantial economic value.~~

~~Any operation shall continue no longer than the minimum time required to prevent the situations identified in (g)(2)(B) of this condition.~~

7. B.14 Multiple Exceedances has been deleted, because 326 IAC 2-7-5(1)(E) has been repealed.

~~B.14 Multiple Exceedances [326 IAC 2-7-5(1)(E)]~~

~~Any exceedance of a permit limitation or condition contained in this permit, which occurs contemporaneously with an exceedance of an associated surrogate or operating parameter established to detect or assure compliance with that limit or condition, both arising out of the same act or occurrence, shall constitute a single potential violation of this permit.~~

8. B.14 Prior Permit Superseded was added to the permit to help clarify the intent of the new rule 326 IAC 2-1.1-9.5.

B.14 Prior Permits Superseded [326 IAC 2-1.1-9.5]

(a) All terms and conditions of previous permits issued pursuant to permitting programs approved into the state implementation plan have been either

(1) incorporated as originally stated,

(2) revised, or

(3) deleted

by this permit.

(b) All previous registrations and permits are superseded by this permit.

9. Condition (b) from B.13 Permit Shield has been deleted. Since B.14 Prior Permits Superceded has been added to the permit, it is not necessary for this statement to be in this condition.

B.13 Permit Shield [326 IAC 2-7-15] [326 IAC 2-7-20] [326 IAC 2-7-12]

~~(b) This permit shall be used as the primary document for determining compliance with applicable requirements established by previously issued permits. All previously issued operating permits are superseded by this permit.~~

10. The IDEM, OAQ, has revised Condition B.15 Deviations from Permit Requirements and Conditions and certain Parametric Monitoring conditions in the D section of the permit to address concerns regarding the independent enforceability of permit conditions [see 40 CFR 70.6(a)(6)(i)]. The Parametric Monitoring conditions have been revised to establish normal operating conditions for the emission unit or control device and to require implementation of the compliance response plan when monitoring indicates operation is outside the normal range. Language that inferred that operating outside of the normal range could be considered by itself to be a deviation was removed. B.15 was revised to remove language that could be considered to grant exemptions from permit requirements and to clarify reporting obligations.

B.15 Deviations from Permit Requirements and Conditions [326 IAC 2-7-5(3)(C)(ii)]

(a) Deviations from any permit requirements (for emergencies see Section B - Emergency Provisions), the probable cause of such deviations, and any response steps or preventive measures taken shall be reported to:

Indiana Department of Environmental Management
Compliance Data Section, Office of Air Quality

100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

using the attached Quarterly Deviation and Compliance Monitoring Report, or its equivalent. ~~Deviations that are required to be reported by an applicable requirement~~ **A deviation required to be reported pursuant to an applicable requirement that exists independent of this permit,** shall be reported according to the schedule stated in the applicable requirement and ~~do~~ **does** not need to be included in this report.

The ~~notification by the Permittee~~ **Quarterly Deviation and Compliance Monitoring Report** does require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(b) A deviation is an exceedance of a permit limitation or a failure to comply with a requirement of the permit ~~or a rule. It does not include:~~

~~(1) An excursion from compliance monitoring parameters as identified in Section D of this permit unless tied to an applicable rule or limit; or~~

~~(2) Failure to implement elements of the Preventive Maintenance Plan unless such failure has caused or contributed to a deviation.~~

~~A Permittee's failure to take the appropriate response step when an excursion of a compliance monitoring parameter has occurred is a deviation.~~

(c) Emergencies shall be included in the Quarterly Deviation and Compliance Monitoring Report.

D.2.9 Parametric Monitoring

The Permittee shall record the total static pressure drop across the baghouses V2, V4, V5, V6, V7, V8, V9, and EU2 used in conjunction with the table, capsule, and phase IIIA manufacturing facilities, at least once per shift when these facilities are in operation when venting to the atmosphere. ~~Unless operated under conditions for which the Compliance Response Plan specifies otherwise,~~ **When for any one reading, the** pressure drop across the baghouse ~~shall be maintained within~~ **is outside** the range of 3.0 and 6.0 inches of water or a range established during the latest stack test. ~~The~~ **,the Permittee shall take reasonable response steps in accordance with Section C-** Compliance Response Plan **- Failure to Take Response Steps**. ~~for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.~~ **A pressure reading that is outside the above mentioned range is not a deviation from this permit.** Failure to take response steps in accordance with Section C - Compliance ~~Monitoring~~ **Response** Plan - **Preparation, Implementation, Records, and Reports**, shall be considered a violation of this permit.

11. Part 70 requires any application form, report, or compliance certification to be certified by the Responsible Official. IDEM, OAQ has revised C.7 Asbestos Abatement Projects to clarify that the asbestos notification does not require a certification by the responsible official, but it does need to be certified by the owner or operator. IDEM, OAQ has revised C.16 Actions Related to Noncompliance Demonstrated by a Stack Test; a certification by the responsible official is required for the notification sent in response to non-compliance with a stack test.

C.7 Asbestos Abatement Projects [326 IAC 14-10] [326 IAC 18] [40 CFR 61, Subpart M]

(a) Notification requirements apply to each owner or operator. If the combined amount of regulated asbestos containing material (RACM) to be stripped, removed or disturbed is

at least 260 linear feet on pipes or 160 square feet on other facility components, or at least thirty-five (35) cubic feet on all facility components, then the notification requirements of 326 IAC 14-10-3 are mandatory. All demolition projects require notification whether or not asbestos is present.

(b) The Permittee shall ensure that a written notification is sent on a form provided by the Commissioner at least ten (10) working days before asbestos stripping or removal work or before demolition begins, per 326 IAC 14-10-3, and shall update such notice as necessary, including, but not limited to the following:

(1) When the amount of affected asbestos containing material increases or decreases by at least twenty percent (20%); or

(2) If there is a change in the following:

(A) Asbestos removal or demolition start date;

(B) Removal or demolition contractor; or

(C) Waste disposal site.

(c) The Permittee shall ensure that the notice is postmarked or delivered according to the guidelines set forth in 326 IAC 14-10-3(2).

(d) The notice to be submitted shall include the information enumerated in 326 IAC 14-10-3(3).

All required notifications shall be submitted to:

Indiana Department of Environmental Management
Asbestos Section, Office of Air Quality
100 North Senate Avenue, P.O. Box 6015
Indianapolis, Indiana 46206-6015

The notice shall include a signed certification from the owner or operator that the information provided in this notification is correct and that only Indiana licensed workers and project supervisors will be used to implement the asbestos removal project. The notifications do not require a certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

(e) Procedures for Asbestos Emission Control
The Permittee shall comply with the applicable emission control procedures in 326 IAC 14-10-4 and 40 CFR 61.145(c). Per 326 IAC 14-10-4, emission control requirements are applicable for any removal or disturbance of RACM greater than three (3) linear feet on pipes or three (3) square feet on any other facility components or a total of at least 0.75 cubic feet on all facility components.

(f) Indiana Accredited Asbestos Inspector
The Permittee shall comply with 326 IAC 14-10-1(a) that requires the owner or operator, prior to a renovation/demolition, to use an Indiana Accredited Asbestos Inspector to thoroughly inspect the affected portion of the facility for the presence of asbestos. The requirement that the inspector be accredited, pursuant to the provisions of 40 CFR 61, Subpart M, is federally enforceable.

C.16 Actions Related to Noncompliance Demonstrated by a Stack Test [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) When the results of a stack test performed in conformance with Section C - Performance Testing, of this permit exceed the level specified in any condition of this permit, the Permittee shall take appropriate response actions. The Permittee shall submit a description of these response actions to IDEM, OAQ, within thirty (30) days of receipt of the test results. The Permittee shall take appropriate action to minimize excess emissions from the affected facility while the response actions are being implemented.

(b) A retest to demonstrate compliance shall be performed within one hundred twenty (120) days of receipt of the original test results. Should the Permittee demonstrate to IDEM, OAQ that retesting in one-hundred and twenty (120) days is not practicable, IDEM, OAQ may extend the retesting deadline.

(c) IDEM, OAQ reserves the authority to take any actions allowed under law in response to noncompliant stack tests.

The documents submitted pursuant to this condition do ~~not~~ require the certification by the "responsible official" as defined by 326 IAC 2-7-1(34).

12. The IDEM, OAQ has restructured C.15 to clarify the contents and implementation of the compliance response plan. The name of the condition has changed to better reflect the contents of the condition. The language regarding the OAQ's discretion to excuse failure to perform monitoring under certain conditions has been deleted. The OAQ retains this discretion to excuse minor incidents of missing data; however, it is not necessary to state criteria regarding the exercise of that discretion in the permit. In C.15 (c)(2) "administrative amendment" has been revised to "minor permit modification", because 326 IAC 2-7-11(a)(7) has been repealed. The title Compliance Monitoring Plan has been changed to Compliance Response Plan throughout the permit.

C.15 Compliance ~~Monitoring~~ **Response** Plan - ~~Failure to Take Response Steps~~ **Preparation, Implementation, Records, and Reports** [326 IAC 2-7-5] [326 IAC 2-7-6]

(a) The Permittee is required to **prepare** ~~implement: a compliance monitoring plan to ensure that reasonable information is available to evaluate its continuous compliance with applicable requirements. The compliance monitoring plan can be either an entirely new document, consist in whole of information contained in other documents, or consist of a combination of new information and information contained in other documents. If the compliance monitoring plan incorporates by reference information contained in other documents, the Permittee shall identify as part of the compliance monitoring plan the documents in which the information is found. The elements of the compliance monitoring plan are:~~

~~(1) This condition;~~

~~(2) The Compliance Determination Requirements in Section D of this permit;~~

~~(3) The Compliance Monitoring Requirements in Section D of this permit;~~

~~(4) The Record Keeping and Reporting Requirements in Section C (General Record Keeping Requirements, and General Reporting Requirements) and in Section D of this permit; and~~

~~(5)~~ ~~A~~ **a** Compliance Response Plan (CRP) for each compliance monitoring condition of this permit. **A** CRP~~'s~~ shall be submitted to IDEM, OAQ upon request ~~and shall be subject to review and approval by IDEM, OAQ~~. The CRP shall be prepared within ninety (90) days after issuance of this permit by the Permittee**, supplemented from time to time by the Permittee,** ~~and~~ maintained on site, and ~~is~~ comprised of:

~~(A)~~**(1)** Reasonable response steps that may be implemented in the event that ~~compliance related information indicates that~~ a response step is needed pursuant to the requirements of Section D of this permit; and **an expected timeframe for taking reasonable response steps.**

~~(B) A time schedule for taking reasonable response steps including a schedule for devising additional response steps for situations that may not have been predicted.~~

(2) If, at any time, the Permittee takes reasonable response steps that are not set forth in the Permittee's current Compliance Response Plan and the Permittee documents such response in accordance with subsection (e) below, the Permittee shall amend its Compliance Response Plan to include such response steps taken.

(b) For each compliance monitoring condition of this permit, reasonable response steps shall be taken when indicated by the provisions of that compliance monitoring condition **as follows:** ~~Failure to take reasonable response steps may constitute a violation of the permit.~~

(1) Reasonable response steps shall be taken as set forth in the Permittee's current Compliance Response Plan; or

(2) If none of the reasonable response steps listed in the Compliance Response Plan is applicable or responsive to the excursion, the Permittee shall devise and implement additional response steps as expeditiously as practical. Taking such additional response steps shall not be considered a deviation from this permit so long as the Permittee documents such response steps in accordance with this condition.

(1) If the Permittee determines that additional response steps would necessitate that the emissions unit or control device be shut down, the IDEM, OAQ shall be promptly notified of the expected date of the shut down, the status of the applicable compliance monitoring parameter with respect to normal, and the results of the actions taken up to the time of notification.

(2) Failure to take reasonable response steps shall constitute a violation of the permit.

(c) ~~Upon investigation of a compliance monitoring excursion, the~~ **The** Permittee is ~~excused from taking~~ **not required to take any** further response steps for any of the following reasons:

(1) A false reading occurs due to the malfunction of the monitoring equipment **and** ~~This shall be an excuse from taking further response steps providing that~~ prompt action was taken to correct the monitoring equipment.

(2) The Permittee has determined that the compliance monitoring parameters established in the permit conditions are technically inappropriate, has previously submitted a request for ~~an administrative amendment~~ **a minor permit modification** to the permit, and such request has not been denied.

(3) An automatic measurement was taken when the process was not operating.

(4) The process has already returned or is returning to operating within "normal" parameters and no response steps are required.

(d) When implementing reasonable steps in response to a compliance monitoring condition, if the Permittee determines that an exceedance of an emission limitation has occurred, the Permittee shall report such deviations pursuant to Section B-Deviations from Permit Requirements and Conditions.

~~(d)~~**(e)** ~~Records shall be kept of all instances in which the compliance related information was not met and of all response steps taken.~~ **The Permittee shall record all instances when response steps are taken.** In the event of an emergency, the provisions of 326 IAC 2-7-16 (Emergency Provisions) requiring prompt corrective action to mitigate emissions shall prevail.

~~(e)~~**(f)** **Except as otherwise provided by a rule or provided specifically in Section D,** all monitoring **as** required in Section D shall be performed ~~at all times~~ **when** the ~~equipment~~ **emission unit** is operating, **except for time necessary to perform quality assurance and maintenance activities.** ~~If monitoring is required by Section D and the equipment is not operating, then the Permittee may record the fact that the equipment is not operating or perform the required monitoring.~~

~~(f) At its discretion, IDEM may excuse the Permittee's failure to perform the monitoring and record keeping as required by Section D, if the Permittee provides adequate justification and documents that such failures do not exceed five percent (5%) of the operating time in any quarter. Temporary, unscheduled unavailability of qualified staff shall be considered a valid reason for failure to perform the monitoring or record keeping requirements in Section D.~~

March 25, 2002

Indiana Department of Environmental Management
Office of Air Quality

Technical Support Document (TSD) for a Part 70 Operating Permit

Source Background and Description

Source Name: Schwarz Pharma Manufacturing, Inc.
Source Location: 1101 C Avenue West, Seymour, Indiana 47274
County: Jackson
SIC Code: 2834
Operation Permit No.: T071-7162-00023
Permit Reviewer: ERG/AB

The Office of Air Quality (OAQ) has reviewed a Part 70 permit application from Schwarz Pharma Manufacturing Inc. relating to the operation of a batch pharmaceutical manufacturing facility producing liquid, capsule, and tablet pharmaceuticals.

Permitted Emission Units and Pollution Control Equipment

This stationary source consists of the following emission units and pollution control devices:

(a) Two (2) 20.9 MMBtu per hour natural gas-fired boilers equipped with low-NOx burners. These units were constructed in 2000.

(b) One (1) tablet manufacturing department, constructed in 1993, consisting of

(1) One (1) granulation department consisting of four (4) mixers, six (6) comminuting mills and four (4) electric production ovens, equipped with a baghouse for particulate matter control, identified as V2.

(2) One (1) tablet compression department consisting of one (1) granulator, and eleven (11) tablet presses, equipped with a baghouse for particulate matter control, identified as V4.

(3) One (1) tablet coating department consisting of two (2) hi-coaters, equipped with two (2) baghouses for particulate mater control, identified as V6 and V9.

(c) One (1) capsule manufacturing department, constructed in 1993, consisting of coating pans, auger feeders and several kettles, equipped with a baghouse for particulate matter control, identified as V5.

(d) One (1) Phase IIIA production area, identified as emission unit 02 (EU-02). This area manufactures several products, which involve tablet formulation, compression and filling of tablets, capsules and aqueous coating of tablets. This production area is rated at 1,960.3 pounds per batch (lbs/batch) of raw material and the PM emissions are controlled by baghouse EU-02. The Phase IIIA production area uses 660 pounds per batch (lbs/batch) of ethanol in the coating process. This production area includes one (1) flo-coater for the application of sustained release coating, equipped with two (2) baghouses, identified as V7 and V8. These units were constructed in 2000.

(e) Cleaning and sanitizing operations using isopropanol, bleaches, and non-solvent based sanitizing agents.

(f) One (1) Colyte production area (identified as emission unit 01 (EU-01)), used to manufacture different types of Colyte, involving a dry mix blending operation, product container filling and labeling. This production area was constructed in 2000 and is rated at 3,956 pounds of raw material per batch (lbs/batch) and the PM emissions are controlled by baghouse EU-01.

Insignificant Activities

The source also consists of the following insignificant activities, as defined in 326 IAC 2-7-1(21):

(a) Natural gas-fired combustion sources with heat input equal to or less than ten million (10,000,000) Btu per hour, constructed between 1985 and 2000, including:

(1) One (1) natural gas-fired boiler with maximum capacity of 4.8 MMBtu per hour [326 IAC 6-2-4].

(2) One (1) natural gas-fired boiler with maximum capacity of 3.6 MMBtu per hour [326 IAC 6-2-4], and

(b) The following equipment related to manufacturing activities not resulting in the emission of HAPs: brazing equipment, cutting torches, soldering equipment, welding equipment [326 IAC 6-3].

(c) Paved and unpaved roads and parking lots with public access [326 IAC 6-4].

(d) A laboratory as defined in 326 IAC 2-7-1(20)(C).

(e) Other categories with emissions below insignificant thresholds:

(1) A liquid pharmaceutical manufacturing facility, consisting of liquid blending, filtration, and packaging, emitting less than three (3) pounds per hour of VOC.

(2) One (1) product weigh-up department for weighing the tablet, capsule, and liquid departments, consisting of six (6) weigh-up rooms with drums, scoops and scales, with emissions exhausted through one (1) baghouse for particulate matter control, identified as V1. Particulate matter emissions before the baghouse are less than five (5) pounds per hour [326 IAC 6-3].

New Emission Units and Pollution Control Equipment

There are no new emission units at this source.

Existing Approvals

The source has been operating under previous approvals including, but not limited to, the following:

(a) CP 071-2389-00023, issued on February 3, 1993.

(b) CP 071-3874-00023, issued on January 25, 1995.

(c) Minor Source Modification 071-11653-00023, issued on April 20, 2000.

(d) Minor Source Modification 071-12424-00023, issued on August 18, 2000.

All conditions from previous approvals were incorporated into this Part 70 permit except the following:

(a) CP 071-2389-00023, issued on February 3, 1993.
Condition No. 4: That the total amount of organic solvents used in the manufacturing facility minus the amount of organic solvents shipped off site as waste shall be limited to 3.33 tons per month, and shall not exceed a rolling average of greater than 24 tons during the last twelve month period. Therefore, the new facilities general reduction requirements, rule, 326 IAC 8-1-6, will not apply.

Reason not incorporated: Pursuant to 326 IAC 8-1-6 and CP 071-3874-00023, issued on January 25, 1995, the source installed Best Available Control Technology (BACT) thereby eliminating the need for the VOC emission limit and avoiding 326 IAC 8-1-6.

(b) CP 071-3874-00023, issued on January 25, 1995.
Condition No. 6(a)(2): Use of flo-coaters to replace the current sustained release coating operations in the capsule manufacturing area. The flo-coater will improve the quality of the products resulting in less scraping of products, will reduce the amount of in-process testing and will allow reduction in solvents.

Reason not incorporated: Schwartz Pharma has implemented the flo-coater for all but one of the capsule products manufactured at this plant. The flo-coater could not be implemented for the manufacturer of Niferex 150 due to technical problems associated with the flo-coater. Although this product cannot be manufactured using the flo-coater, Schwarz Pharma has stated that it uses a coating that does not contain any volatile organic compounds (VOCs) to manufacture this product. Based on this information, IDEM has determined that Schwarz Pharma is in compliance with this BACT condition. In order to clarify the original intent of this BACT requirement, IDEM, OAQ has revised the language for this condition as follows:

> "For capsule manufacturing, the Permittee shall use flo-coaters for applying sustained release coatings for all products in which volatile organic compounds (VOCs) are used."

(c) CP 071-3874-00023, issued on January 25, 1995.
Condition No. 6(a)(1): Elimination of isopropanol from cleaning operations.

Reason not incorporated: In a revised BACT analysis submitted to IDEM in May 2000, Schwarz Pharma stated that the elimination of isopropanol should not be considered as BACT for pharmaceutical manufacturing facilities because this solvent is the most appropriate for certain processes. Based on the revised BACT, IDEM, OAQ has determined that BACT for the cleaning and sanitizing operations is as follows:

"The use of isopropanol in cleaning and sanitizing operations shall be minimized by using bleaches and other non-solvent sanitizers where appropriate."

Schwarz Pharma has already implemented this revised BACT and has reduced isopropanol usage by 96.4% since 1995.

(d) Construction Permit 071-3874-00023, issued on January 25, 1995.
Condition No. 4: That particulate matter emissions from the boilers shall comply with 326 IAC 6-2 (Particulate Emission Limitations for Sources of Indirect Heating). Particulate matter emissions from the boilers shall be limited to 0.6 pounds per million BTU heat input, pursuant to that rule.

Reason not incorporated: This condition refers to the two (2) 4.2 MMBtu per hour original boilers. Both of these boilers are out of service and no longer operational.

Air Pollution Control Justification as an Integral Part of the Process

The company has submitted the following justification such that the baghouses identified as V1, V2, V4, V5, V6, V7 and V8 be considered as an integral part of the tablet, capsule, and liquid pharmaceutical manufacturing process.

The source claims that the baghouses identified as V1, V2, V4, V5, V6, V7, and V8 are required emission control units under 21CFR 211.46(c), Subpart C. This FDA regulation covers ventilation, air filtration, and air heating and cooling systems for facilities that manufacture pharmaceuticals.

During the review of the Title V permit application, IDEM, OAQ evaluated the justification and determined that the baghouses should not be considered integral parts of the pharmaceutical manufacturing processes, because they are required only by FDA, which may modify or revoke 21 CFR 211.46(c), Subpart C at any time. FDA regulations do not exempt IDEM, OAQ rules. Therefore, the permitting level will be determined using the potential to emit before the baghouses.

Enforcement Issue

There are no enforcement actions pending.

Recommendation

The staff recommends to the Commissioner that the Part 70 permit be approved. This recommendation is based on the following facts and conditions:

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant.

An administratively complete Part 70 permit application for the purposes of this review was received on November 14, 1996. Additional information was received on December 16, 1996, March 27, 1998, July 7, 1998, August 21, 1998, April 27, 2000, May 8, 2000, October 3, 2000, October 5, 2000, November 15, 2000, January 19, 2001, June 6, 2001, July 11, 2001, and July 26, 2001.

There was no notice of completeness letter mailed to the source.

Emission Calculations

See Appendix A of this document for detailed emissions calculations (pages 1 through 9).

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA.”

This table reflects the PTE before controls. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	204.9
PM-10	204.9
SO_2	0.2

Pollutant	Potential To Emit (tons/year)
VOC	215.6
CO	15
NO_x	8.8

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

HAP's	Potential To Emit (tons/year)
Methanol	90
Methylene Chloride	78
TOTAL	168

(a) The potential to emit (as defined in 326 IAC 2-1.1-1(16)) of PM-10 and VOC are equal to or greater than 100 tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.

(b) The potential to emit (as defined in 326 IAC 2-1.1-1(16)) of any single HAP is equal to or greater than ten (10) tons per year and the potential to emit (as defined in 326 IAC 2-7-1(29)) of a combination HAPs is greater than or equal to twenty-five (25) tons per year. Therefore, the source is subject to the provisions of 326 IAC 2-7.

Actual Emissions

The following table shows the actual emissions from the source. This information reflects the 1999 OAQ emission data.

Pollutant	Actual Emissions (tons/year)
PM	-----
PM-10	1
SO_2	0
VOC	29
CO	3
NO_x	6
HAP (specify)	-----

Potential to Emit After Issuance

The table below summarizes the potential to emit, reflecting all limits, of the significant emission units after controls. The control equipment is considered federally enforceable only after issuance of this Part 70 operating permit.

	Potential to Emit (tons/year)						
Process/facility	PM	PM-10	SO_2	VOC	CO	NO_X	HAPs
Boilers	1.4	1.4	0.2	8.0	15	8.8	Negligible
Tablet Manufacturing Department	0.03	0.03	0	134	0	0	(a)
Cleaning and Sanitizing Operations	0	0	0		0	0	

	Potential to Emit (tons/year)						
Process/facility	PM	PM-10	SO_2	VOC	CO	NO_X	HAPs
Capsule Manufacturing Department	0.02	0.02	0		0	0	
Colyte Manufacturing Department	6.5 x 155	6.5 x 155	0	0	0	0	0
Phase IIIA Production Area	1.3×10^{-5}	1.3×10^{-5}	0	0	0	0	0
Total Emissions	1.45	1.45	0.2	142	15	8.8	(a)

(a) Pursuant to 40 CFR 63, Subpart GGG, HAP emissions from individual process vents shall be less than 50 ppmv.

County Attainment Status

The source is located in Jackson County.

Pollutant	Status
PM-10	Attainment
SO_2	Attainment
NO_2	Attainment
Ozone	Attainment
CO	Attainment
Lead	Attainment

(a) Volatile organic compounds (VOC) and oxides of nitrogen (NO_x) are precursors for the formation of ozone. Therefore, VOC and NO_x emissions are considered when evaluating the rule applicability relating to the ozone standards. Jackson County has been designated as attainment or unclassifiable for ozone. Therefore, VOC and NO_x emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

(b) Jackson County has been classified as attainment or unclassifiable for PM-10, SO_2, NO_2, CO and lead. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2 and 40 CFR 52.21.

Part 70 Permit Conditions

This source is subject to the requirements of 326 IAC 2-7, pursuant to which the source has to meet the following:

(a) Emission limitations and standards, including those operational requirements and limitations that assure compliance with all applicable requirements at the time of issuance of Part 70 permits.

(b) Monitoring and related record keeping requirements which assume that all reasonable information is provided to evaluate continuous compliance with the applicable requirements.

Federal Rule Applicability

(a) The two (2) 20.9 MMBtu/hour boilers are subject to the New Source Performance Standard, 40 CFR 60, Subpart Dc (Small Industrial - Commercial - Institutional Steam Generator Units) (326 IAC 12). Under this rule the permittee is not required to comply with the specific emission limitations because the boilers are only fired on natural gas. The source is required to maintain records according to 40 CFR 60.48c.

(b) No other New Source Performance Standards are applicable to this source.

(c) This source is subject to the National Emission Standards for Hazardous Air Pollutants (NESHAP) 40 CFR 63, Subpart GGG - National Emission Standards for Pharmaceuticals Production (326 IAC 20) because the source:

(1) Manufactures pharmaceutical products;

(2) Uses solvents that contain hazardous air pollutants (HAPs);

(3) Is a major source as defined in Section 112(a) of the Clean Air Act; and

(4) Is an existing source constructed prior to April 2, 1997.

Although the source is subject to 40 CFR 63, Subpart GGG, no control requirements apply because the source does not have any emission points regulated by the rule. The source does not generate wastewater streams from its pharmaceutical manufacturing processes, has no storage tanks meeting the criteria in 40 CFR 63.1253(a), and has no pumps, compressors, agitators, pressure relief devices, sampling connection systems, open ended values or lines, valves, connectors, instrumentation systems, control devices, or closed-vent systems intended to be used for HAPs. All vents have HAP concentrations in their vent stream less than 50 ppmv; therefore, these vents are not considered “process vents” as defined by Subpart GGG and are not regulated.

Pursuant to 40 CFR 63, Subpart GGG, the Permittee shall comply with the following requirements of this NESHAP by September 21, 2001.

Emissions Limitations:

Pursuant to 40 CFR 63.1251 (National Emission Standards for Pharmaceuticals Production), the Permittee shall comply with the following HAP emission limitation on or before September 21, 2001. HAP emissions from individual process vents shall be less than 50 ppmv. Any changes to the process that would increase emissions from any individual process vent to greater than 50 ppmv requires prior approval from IDEM, OAQ.

Compliance Determination:

Pursuant to 40 CFR 63, Subpart GGG (National Emission Standards for Pharmaceuticals Production), HAP emissions from individual process vents shall be determined using one of the following methods:

(a) Process knowledge that indicates no HAP are present in the emission stream

(b) Testing using Methods 18 of 40 CFR 63, Appendix A;

(c) Testing using test methods validated according to the procedures in Method 301 of 40 CFR 60, of Appendix A; or

(d) Engineering assessments as described in 40 CFR 63.1257(d)(2)(ii), which includes by is not limited to:

(1) Previous test results, provided the tests are representative of current operating practices at the facility.

(2) Bench-scale or pilot test data representative of the process under representative operating conditions.

(3) Maximum flow rate, HAP emission rate, concentration, or other relevant parameter specified or implied within a permit limit applicable to the process vent.

(4) Design analysis based on accepted chemical engineering principles, measurable process parameters, or physical or chemical laws or properties. Examples of analytical methods include, but are not limited to:

(A) Use of material balances based on process stoichiometry to estimate maximum organic HAP concentrations.

(B) Estimation of maximum flow rate based on physical equipment design such as pump or blower capacities.

(C) Estimation of HAP concentrations based on saturation conditions.

(5) All data, assumptions, and procedures used in the engineering assessment shall be documented in accordance with 40 CFR 63.1260(e). Data or other information supporting a finding that the emissions estimation equations are inappropriate shall be reported in the precompliance report.

Record Keeping Requirements:

Pursuant to 40 CFR 63, Subpart A and 40 CFR 63, Subpart GGG, the Permittee shall maintain the following records:

(a) Copies of all records and reports required by 40 CFR 63, Subpart GGG.

(b) Copies of the current and superceded versions of the Startup, Shutdown, and Malfunction plan.

(c) Copies of startup, shutdown and malfunction records required under 40 CFR 63, Subpart GGG.

Reporting:

(a) Pursuant to 40 CFR 63, Subpart A, the Permittee shall submit an initial notification to the Administrator not later than 120 calendar days after the effective date of 40 CFR 63, Subpart GGG. The initial notification shall contain:

(1) The name and address of the owner or operator;

(2) The address (i.e., physical location) of the emission units;

(3) An identification of the relevant standard, or other requirement, that is the basis of the notification and the date on which the source is required to be in compliance; and

(4) A statement indicating whether the source is a major source or an area source.

(b) Pursuant to 40 CFR 63, Subpart GGG, the Permittee shall submit a Precompliance report at least 6 months prior to the compliance date. The Administrator shall have 90 days to approve or disapprove the plan. The plan shall be considered approved if the Administrator either approves or disapproves the plan in writing or fails to disapprove the plan in writing. If the request is denied, the Permittee must still be in compliance with the standard by the compliance date. The Precompliance report shall data and rationale used to support an engineering assessment to calculate uncontrolled emissions from process vents as required in 40 CFR 63.1257(d)(2)(ii).

(c) Pursuant to 40 CFR 63.9, the Permittee shall submit a Notification of Compliance Status Report no later than 150 days after the compliance date. This report shall include:

(1) The results of any applicability determinations, emission calculations, or analyses used to identify and quantify HAP emissions from the affected source.

(2) The results of emissions profiles, performance tests, engineering analyses, design evaluations, or calculations used to demonstrate compliance. For performance tests, results should include descriptions of sampling and analysis procedures and quality assurance procedures.

(3) Descriptions of monitoring devices, monitoring frequencies, and the values of monitored parameters established during the initial compliance determinations, including data and calculations to support the levels established.

(4) Listing of all operating scenarios.

(5) Description of worst-case operating and /or testing conditions for control devices.

(6) Identification of emission points subject to overlapping requirements described in 40 CFR 63.1250(h) and the authority under which the Permittee will comply.

(d) Pursuant to 40 CFR 63.1260(g), the Permittee shall submit Periodic Reports semiannually, beginning 60 operating days after the end of the applicable reporting period. The first report shall be submitted no later than 240 days after the date of Notification of Compliance Status is due and shall cover the 6-month period beginning on the date of Notification of Compliance Status is due.

(e) Pursuant to 40 CFR 63.1260(h), the Permittee shall submit a quarterly report whenever a process change is made or a change in any of the information submitted in the Notification of Compliance Status Report. The report may by submitted as part of the next Periodic report required under 40 CFR 63.1260(g). The report shall include:

(1) A brief description of the process change.

(2) A description of any modifications to the standard procedures or quality assurance procedures.

(3) Revisions to any of the information reported in the original Notification of Compliance Status Report.

(4) Information required by the Notification of Compliance Report under 40 CFR 63.1260(f).

(d) No other NESHAPs are applicable to this source.

State Rule Applicability - Entire Source

326 IAC 2-6 (Emission Reporting)

This source is subject to 326 IAC 2-6 (Emission Reporting), because it has the potential to emit more than one hundred (100) tons per year of PM and VOC. Pursuant to this rule, the owner/operator of the source must annually submit an emission statement for the source. The annual statement must be received by July 1 of each year and contain the minimum requirement as specified in 326 IAC 2-6-4. The submittal should cover the period defined in 326 IAC 2-6-2(8)(Emission Statement Operating Year).

The source will be required to annually submit a statement of the actual emissions of all federally regulated pollutants from the source, for the purpose of fee assessment.

326 IAC 5-1 (Opacity Limitations)

Pursuant to 326 IAC 5-1-2 (Opacity Limitations), except as provided in 326 IAC 5-1-3 (Temporary Alternative Opacity Limitations), opacity shall meet the following, unless otherwise stated in this permit:

(a) Opacity shall not exceed an average of forty percent (40%) any one (1) six (6) minute averaging period as determined in 326 IAC 5-1-4.

(b) Opacity shall not exceed sixty percent (60%) for more than a cumulative total of fifteen (15) minutes (sixty (60) readings as measured according to 40 CFR 60, Appendix A, Method 9 or fifteen (15) one (1) minute nonoverlapping integrated averages for a continuous opacity monitor) in a six (6) hour period.

326 IAC 2-4.1-1 (New Source Toxics Control)

The provisions of 326 IAC 2-4.1-1 (New Source Toxics Control) are not applicable to the tablet and capsule manufacturing areas because they were constructed prior to July 27, 1997. The colyte and phase III A manufacturing areas, which were constructed in 2000, are not subject to 326 IAC 2-4.1-1 because no hazardous air pollutants are used in these areas.

326 IAC 8-5-2 (Synthesized Pharmaceutical Manufacturing Operations)

The source is not subject to the requirements of 326 IAC 8-5-2, because no chemical synthesis occurs at the facility.

State Rule Applicability - Individual Facilities

326 IAC 6-2-4 (Particulate Emission Limitations for Sources of Indirect Heating Constructed After September 21, 1983)

(a) Pursuant to 326 IAC 6-2-4 (Emission Limitations for facilities specified in 326 IAC 6-2-1(d)), the particulate emissions from the 3.6 MMBtu/hour and 4.8 MMBtu/hour boilers shall not exceed 0.6 pounds per MMBtu heat input.

This limit was calculated using the following equation:

$$Pt = \frac{1.09}{Q^{0.26}}$$

Where: Pt = Pounds of PM emitted per million Btu (lb/MMBtu) heat input; and
Q = Total source maximum operating capacity rating in MMBtu/hour

Q includes the capacities from the two natural gas-fired boilers constructed in 1998, rated at 3.6 MMBtu/hour and 4.8 MMBtu/hour.

(b) Pursuant to 326 IAC 6-2-4 (Emission Limitations for facilities specified in 326 IAC 6-2-1(d)), the particulate emissions from the two 20.9 MMBtu/hr boilers shall not exceed 0.4 pound per MMBtu heat input.

This limit was calculated using the following equation:

$$P_t = \frac{1.09}{Q^{0.26}}$$

Where: P_t = Pounds of particulate matter emitted per million Btu (lb/MMBtu) heat input; and
Q = Total source maximum operating capacity rating in million Btu per hour (MMBtu/hr) heat input.

Q includes the capacities from the two (2) 20.9 MMBtu per hour boilers and the two insignificant boilers: the 3.6 MMBtu per hour boiler and the 4.8 MMBtu per hour boiler.

Note: All of the boilers currently located at this plant are subject to the requirements of 326 IAC 6-2-4 because they were constructed after September 21, 1983.

326 IAC 6-3-2 (Process Operations)

Pursuant to CP 071-2389-00023, issued on February 23, 1992, and CP 071-3874-00023, issued on January 25, 1995 the particulate matter (PM) from the tablet manufacturing department and the capsule manufacturing department shall be limited by the following:

Facility	Process Weight (lbs/hr)	PM Emission Limit (lbs/hour)
Tablet Manufacturing Department	26	0.23
Capsule Manufacturing Department	13.8	0.14

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$$E = 4.10\ P^{0.67}$$

where E = rate of emission in pounds per hour and
P = process weight rate in tons per hour

The baghouses identified as V2, V4, V5, V6, V7, and V8 shall be in operation at all times the tablet manufacturing department and the capsule manufacturing department are in operation, in order to comply with this limit.

326 IAC 6-3-2 (Process Operations) Minor Source Modifications 071-11653-00023 and 071-12424-00023, issued on April 20, 2000 and August 18, 2000, respectively, the particulate matter (PM) from the colyte and phase IIIA production facilities shall be limited by the following:

Facility	Process Weight (lbs/hr)	PM Emission Limit (lbs/hour)
Colyte Manufacturing Department	20	0.187
Phase IIIA Production Area	8.8	0.11

Interpolation of the data for the process weight rate up to sixty thousand (60,000) pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

The baghouses (identified as EU-1 and EU-2) shall be in operation at all times the colyte and phase IIIA production facilities are in operation, in order to comply with this limit.

326 IAC 6-3-2 (Process Operations)

Pursuant to 326 IAC 6-3-2 (Process Operations), the allowable PM emission rate from the product weigh-up department and welding equipment shall not exceed the allowable PM emission rate based on the following equation:

Interpolation of the data for the process weight rate up to 60,000 pounds per hour shall be accomplished by use of the equation:

$E = 4.10\ P^{0.67}$ where E = rate of emission in pounds per hour; and
P = process weight rate in tons per hour

326 IAC 8-1-6 (Organic Solvent Emission Limitations)

The source became subject to 326 IAC 8-1-6 (New Facilities; General Reduction Requirements) in 1995, when the source indicated that it could no longer comply with the voluntary 24 tons per year VOC limit contained in CP 071-2389-00018 (issued February 3, 1993).

Pursuant to 326 IAC 8-1-6, the Best Available Control Technology (BACT) for the control of volatile organic compounds shall be:

(a) Process Modifications:

(1) For capsule manufacturing, the Permittee shall use flo-coaters for applying sustained release coatings for all products in which volatile organic compounds (VOCs) are used.

(2) The capture and off-site disposal of VOC containing chemicals,

(3) Solvent handling procedures (currently being conducted):

(A) Solvents are stored in sealed 55-gallon drums until utilized in the manufacturing process.

(B) The drums are kept sealed except when solvents are withdrawn.

(C) The solvents are extracted from the drums using a dedicated pump.

(D) If one half of the drum content is needed, the entire drum can be transported to the manufacturing area for disposing.

(E) If less than one half of the content of the drum is to be used, the needed portion is transported to the process area in a covered container.

(F) When the manufacturing process requires other chemicals to be dissolved in liquid, the process is conducted in covered vessels.

(G) The use of isopropanol in cleaning and sanitizing operations shall be minimized by using bleaches and other non-solvent sanitizers where appropriate.

(4) The BACT shall be implemented such that:

(A) Implementation of the flo-coater shall reduce VOC emissions by 18%.

(B) The solvents shall be disposed off-site in accordance with the applicable hazardous waste rule found in 40 CFR part 260 to part 272, and shall reduce VOC emissions by 8%.

(C) The on-going solvent handling procedures shall reduce VOC emissions by 0.5%.

(D) The minimization of isopropanol in cleaning and sanitizing operations shall reduce isopropanol emissions by 8%.

The implementation of this BACT shall result in a total VOC reduction of 34.5% from 1995 VOC emission levels. A log of information necessary to document compliance with the BACT shall be maintained by the Permittee. These records shall be kept for at least one (1) year after the implementation of each control technique in the BACT, and made available upon request by IDEM, OAQ.

Compliance Requirements

Permits issued under 326 IAC 2-7 are required to ensure that sources can demonstrate compliance with applicable state and federal rules on a more or less continuous basis. All state and federal rules contain compliance provisions, however, these provisions do not always fulfill the requirement for a more or less continuous demonstration. When this occurs IDEM, OAQ, in conjunction with the source, must develop specific conditions to satisfy 326 IAC 2-7-5. As a result, compliance requirements are divided into two sections: Compliance Determination Requirements and Compliance Monitoring Requirements.

Compliance Determination Requirements in Section D of the permit are those conditions that are found more or less directly within state and federal rules and the violation of which serves as grounds for enforcement action. If these conditions are not sufficient to demonstrate continuous compliance, they will be supplemented with Compliance Monitoring Requirements, also Section D of the permit. Unlike Compliance Determination Requirements, failure to meet Compliance Monitoring conditions would serve as a trigger for corrective actions and not grounds for enforcement action. However, a violation in relation to a compliance monitoring condition will arise through a source's failure to take the appropriate corrective actions within a specific time period.

The compliance monitoring requirements applicable to this source are as follows:

(a) The tablet manufacturing department, the capsule manufacturing department, and the Phase IIIA production area have applicable compliance monitoring conditions as specified below:

(1) Daily visible emissions notations of the tablet, capsule, and Phase IIIA production facilities exhausts shall be performed during normal daylight operations. A trained employee will record whether emissions are normal or abnormal. For processes operated continuously "normal" means those conditions prevailing, or expected to prevail, eighty percent (80%) of the time the process is in operation, not counting startup or shut down time. In the case of batch or discontinuous operations, readings shall be taken during that part of the operation that would normally be expected to cause the greatest emissions. A trained employee is an employee who has worked at the plant at least one (1) month and has been trained in the appearance and characteristics of normal visible emissions for that specific process. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when an abnormal emission is observed.

(2) The Permittee shall record the total static pressure drop across the baghouses (V2, V4, V5, V6, V7, V8 and V9) controlling the tablet, capsule, and Phase IIIA

manufacturing facilities, at least once daily when these manufacturing facilities are in operation. Unless operated under conditions for which the Compliance Response Plan specifies otherwise, the pressure drop across the baghouses (V2, V4, V5, V6, V7, V8 and V9) shall be maintained within the range of 3.0 to 6.0 inches of water or a range established during the latest stack test. The Compliance Response Plan for this unit shall contain troubleshooting contingency and response steps for when the pressure reading is outside of the above mentioned range for any one reading.

(3) In the event that bag failure has been observed:

(A) The affected compartments will be shut down immediately until the failed units have been repaired or replaced. Within eight (8) hours of the determination of failure, response steps according to the timetable described in the Compliance Response Plan shall be initiated. For any failure with corresponding response steps and timetable not described in the Compliance Response Plan, response steps shall be devised within eight (8) hours of discovery of the failure and shall include a timetable for completion. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

(B) For single compartment baghouses, failed units and the associated process will be shut down immediately until the failed units have been repaired or replaced. Operations may continue only if the event qualifies as an emergency and the Permittee satisfies the requirements of the emergency provisions of this permit (Section B - Emergency Provisions).

These monitoring conditions are necessary because the baghouses (V2, V4, V5, V6, V7, V8, and V9) for the tablet, capsule, and Phase IIIA manufacturing facilities must operate properly to ensure compliance with 326 IAC 6-3 (Process Operations) and 326 IAC 2-7 (Part 70).

Conclusion

The operation of this batch pharmaceutical manufacturing facility producing liquid, capsule and tablet pharmaceutical products shall be subject to the conditions of the attached proposed Part 70 Permit No. T071-7162-00023.

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100
Two Industrial Boilers Rated at 20.9 MMBtu/hour

Company Name: **Schwarz Pharma, Inc.**
Address City IN Zip: **1101 "C" Avenue West, Freeman Field, Seymore, IN 47274**
CP: **T071-7162-00023**
Plt ID: **00023**
Reviewer: **ERG/AB**
Date: **09/29/00**

Heat Input Capacity MMBtu/hr	Potential Throughput MMCF/yr
20.9	183.1

Pollutant	PM*	PM10*	SO2	NOx	VOC	CO
Emission Factor in lb/MMCF	7.6	7.6	0.6	50.0 **see below	5.5	84.0
Potential Emission in tons/yr	0.7	0.7	0.1	4.6	0.5	7.7
Total Emissions for both boilers in tons/year	1.4	1.4	0.2	8.8	1	15

*PM emission factor is condensable and filterable PM combined.
**Emission Factors for NOx: Uncontrolled = 100, Low NOx Burner = 50, Low NOx Burners/Flue gas recirculation = 32

Methodology

All emission factors are based on normal firing.
MMBtu = 1,000,000 Btu
MMCF = 1,000,000 Cubic Feet of Gas

Potential Throughput (MMCF) = Heat Input Capacity (MMBtu/hr) x 8,760 hrs/yr x 1 MMCF/1,000 MMBtu
Emission Factors are from AP 42, Chapter 1.4, Tables 1.4-1, 1.4-2, 1.4-3, SCC #1-02-006-02, 1-01-006-02, 1-03-006-02, and 1-03-006-03 (SUPPLEMENT D 3/98)
Emission (tons/yr) = Throughput (MMCF/yr) x Emission Factor (lb/MMCF)/2,000 lb/ton
Note: Check the applicable rules and test methods for PM and PM10 when using the above emission factors to confirm that the correct factor is used (i.e., condensable included/not included).
See page 2 for HAPs emissions calculations.

Appendix A: Emissions Calculations
Natural Gas Combustion Only
MM BTU/HR <100
Small Industrial Boiler
HAPs Emissions

Company Name: **Schwarz Pharma, Inc.**
Address City IN Zip: **1101 "C" Avenue West, Freeman Field, Seymore, IN 47274**
CP: **T071-7162-00023**
Plt ID: **00023**
Reviewer: **ERG/AB**
Date: **09/29/00**

HAPs - Organics

	Benzene	Dichlorobenzene	Formaldehyde	Hexane	Toluene
Emission Factor in lb/MMcf	2.1E-03	1.2E-03	7.5E-02	1.8E+00	3.4E-03
Potential Emission in tons/yr	1.922E-04	1.099E-04	6.866E-03	1.648E-01	3.112E-04
Total Emissions for both Boilers in tons/year	3.845E-04	2.197E-04	1.373E-02	3.296E-01	6.225E-04

HAPs - Metals

	Lead	Cadmium	Chromium	Manganese	Nickel
Emission Factor in lb/MMcf	5.0E-04	1.1E-03	1.4E-03	3.8E-04	2.1E-03
Potential Emission in tons/yr	4.577E-05	1.007E-04	1.282E-04	3.479E-05	1.922E-04
Total Emissions for both Boilers in tons/year	9.154E-05	2.014E-04	2.563E-04	6.957E-05	3.845E-04

Methodology is the same as page 1.

The five highest organic and metal HAPs emission factors are provided above.
Additional HAPs emission factors are available in AP-42, Chapter 1.4.

Appendix A: Emissions Calculations
VOC Emissions from Capsule, Tablet and Cleaning Operations

Company Name: Schwarz Pharma, Inc.
Address City IN Zip: 1101 "C" Avenue West, Freeman Field, Seymore, IN 47274
CP: T071-7162-00023
Plt ID: 00023
Reviewer: ERG/AB
Date: 09/29/00

Material	Density (Lb/Gal)	Weight % VOC	Amount (lbs/batch)	Amount (gallons/batch)	Maximum (batches/hour)	Potential VOC pounds per hour	Potential VOC pounds per day	Potential VOC tons per year
Capsules								
Pharmaceutical glaze used for Guaifenesin & PSE Beads	7.50	65.00%	729.79	97.30	0.040	18.97	455.39	83.11
Total for Capsules								83.11
Tablets								
Isopropanol for Mar-Natal F Tablets	6.58	100.00%	591.08	89.83	0.044	26.01	624.18	113.91
Clear Opacoat for Mar-Natal F Tablets	7.90	70.00%	15.01	1.90	0.044	0.46	11.10	2.02
Total for Tablets								115.94
Cleaning & Sanitization								
Ethanol	6.61	100.00%	5.33	0.81	0.150	0.80	19.00	3.40
Methanol	6.61	100.00%	1.33	0.20	0.150	0.20	6.00	1.00
Isopropanol	6.58	100.00%	1.33	0.20	0.150	0.20	6.00	1.00
Total for Cleaning & Sanitization								5.40
Potential Emissions						**46.64**	**1121.67**	**204.45**

METHODOLOGY

Potential VOC Pounds per Hour = Amount of material (lb/gal) * weight % VOC * Gal of Material (gal/batch) * Maximum (units/hr)
Potential VOC Pounds per Day = Amonut of material (lb/gal) * weight % VOC * Gal of Material (gal/batch) * Maximum (units/hr) * (24 hr/day)
Potential VOC Tons per Year = Amount of material (lb/gal) * weight % VOC * Gal of Material (gal/unit) * Maximum (units/hr) * (8760 hr/yr) * (1 ton/2000 lbs)
Uses emissions from worst case Tablet and Caplet manufacture.

Appendix A: Emissions Calculations
Phase IIIA Production Area
Potential Particulate Matter Emissions

Company Name: **Schwarz Pharma, Inc.**
Address City IN Zip: **1101 "C" Avenue West, Freeman Field, Seymore, IN 47274**
CP: **T071-7162-00023**
Plt ID: **00023**
Reviewer: **ERG/AB**
Date: **09/29/00**

Process	Throughput (lbs/batch)	Maximum Number of Batches per year	Emission Factor (lb PM/ton of Material)	Potential PM Emissions (tons/year)	Control Efficiency (%)	Controlled Emissions (tons/year)
Raw Material Weigh-up	1,690.3	31	5	0.065	99.99	0.000007
Raw Material Mixing	1,690.3	31	5	0.065	99.99	0.000007
Total Emissions				0.131		0.000013

Methodology:
Total Potential PM Emissions (tons/year) = Throughput (lbs/batch) * Number of batches/year * Ton/2000lbs * Emission Factor (lb/ton) * Ton/2000 lbs

Appendix A: Emissions Calculations
Phase IIIA Production Area
Potential VOC Emissions

Company Name: **Schwarz Pharma, Inc.**
Address City IN Zip: **1101 "C" Avenue West, Freeman Field, Seymore, IN 47274**
CP: **T071-7162-00023**
Plt ID: **00023**
Reviewer: **ERG/AB**
Date: **09/29/00**

Process	Throughput (lbs/batch)	Number of Batches per year	Potential VOC Emissions (tons/year)	Uncontrolled Emissions (lbs/hour)
Ethanol Coating	660	31	10.2	2.34

Methodology:
Total Potential VOC Emissions (tons/year) = Throughput (lbs/batch) * Number of batches/year * Ton/2000lbs

Appendix A: Emissions Calculations
Colyte Production Area
Potential Particulate Matter Emissions

Company Name: Schwarz Pharma USA, Inc.
Address City IN Zip: 1101 "C" Avenue West, Freeman Field, Seymore, IN 47274
CP: T071-7162-00023
Plt ID: 00023
Reviewer: ERG/AB
Date: 09/29/00

Process	Throughput (lbs/batch)	Maximum Number of Batches per year	Emission Factor (lb PM/ton of Material)	Uncontrolled Emissions (tons/year)	Control Efficiency (%)	Controlled Emissions (tons/year)
Raw Material Weigh-up	3,956	66	5	0.326	99.99	0.000033
Raw Material Mixing	3,956	66	5	0.326	99.99	0.000033
Total Emissions				0.653		0.000065

Methodology:
Total Potential PM Emissions (tons/year) = Throughput (lbs/batch) * Number of batches/year * Ton/2000lbs * Emission Factor (lb/ton) * Ton/2000 lbs

Appendix A: Emissions Calculations

Particulate Emissions from the Tablet and Capsule Departments

Company Name: **Schwarz Pharma, Inc.**
Address City IN Zip: **1101 "C" Avenue West, Freeman Field, Seymore, IN 47274**
CP: **T071-7162-00023**
Plt ID: **00023**
Reviewer: **ERG/AB**
Date: **09/29/00**

Baghouse	Efficiency (%)**	Maximum PM Collected in Baghouse (lbs/day)**	Maximum PM Collected in Baghouse (tons/year)	Maximum PM Emissions Before Controls (lbs/hour)	Potential PM Emissions Before Controls (tons/year)	Maximum PM Emissions After Controls (tons/year)
V1	99.97	0	0.00	0.00	0.00	0.00
V2	99.97	0	0.00	0.00	0.00	0.00
V4	99.97	5.52	24.18	5.52	24.18	0.01
V5	99.97	17.76	77.79	17.77	77.81	0.02
V6	99.97	9.38	41.08	9.38	41.10	0.01
V9	99.97	9.92	43.45	9.92	43.46	0.01
Total Emissions				42.59	186.56	0.06

** Based on data provided by facility. Facility operates 24 hours per day.

Methodology:

Potential to Emit (tons/yr) = Maximum PM Collected (tons/yr) + Maximum PM Collected (tons/yr) * (1- Efficiency (%) / 100)

Appendix A: Emissions Calculations

Particulate Emissions from the Weigh-up, Tablet, and Capsule Department

Potential Particulate Matter Emissions

Company Name: **Schwarz Pharma, Inc.**
Address City IN Zip: **1101 "C" Avenue West, Freeman Field, Seymore, IN 47274**
CP: **T071-7162-00023**
Plt ID: **00023**
Reviewer: **ERG/AB**
Date: **09/29/00**

Process	Throughput (lbs/hr)	Throughput (tons/year)	Emission Factor (lb PM/ton of Material)	Uncontrolled Emissions (tons/year)	Control Efficiency (%)	Controlled Emissions (tons/year)
Weigh-up Department	740.00	3241.20	5	8.10	99.97	0.002431
Tablet Department	440	1927.20	5	4.82	99.97	0.001445
Capsule Department	300	1314.00	5	3.29	99.97	0.000985
Total				16.206		0.004862

Methodology:

Total Potential PM Emissions (tons/year) = Throughput (tons/year) * Emission Factor (lb PM/ton) * Ton/2000 lbs

electronic report shall be coordinated with the permitting authority. The electronic report(s) shall be submitted no later than 30 days after the end of the calendar quarter and shall be accompanied by a certification statement from the owner or operator, indicating whether compliance with the applicable emission standards and minimum data requirements of this subpart was achieved during the reporting period. Before submitting reports in the electronic format, the owner or operator shall coordinate with the permitting authority to obtain their agreement to submit reports in this alternative format.

[52 FR 47842, Dec. 16, 1987, as amended at 54 FR 51820, 51825, Dec. 18, 1989; 60 FR 28062, May 30, 1995; 61 FR 14031, Mar. 29, 1996; 62 FR 52641, Oct. 8, 1997; 63 FR 49455, Sept. 16, 1998; 64 FR 7464, Feb. 12, 1999]

Subpart Dc—Standards of Performance for Small Industrial-Commercial-Institutional Steam Generating Units

SOURCE: 55 FR 37683, Sept. 12, 1990, unless otherwise noted.

§ 60.40c Applicability and delegation of authority.

(a) Except as provided in paragraph (d) of this section, the affected facility to which this subpart applies is each steam generating unit for which construction, modification, or reconstruction is commenced after June 9, 1989 and that has a maximum design heat input capacity of 29 megawatts (MW) (100 million Btu per hour (Btu/hr)) or less, but greater than or equal to 2.9 MW (10 million Btu/hr).

(b) In delegating implementation and enforcement authority to a State under section 111(c) of the Clean Air Act, §60.48c(a)(4) shall be retained by the Administrator and not transferred to a State.

(c) Steam generating units which meet the applicability requirements in paragraph (a) of this section are not subject to the sulfur dioxide (SO_2) or particulate matter (PM) emission limits, performance testing requirements, or monitoring requirements under this subpart (§§60.42c, 60.43c, 60.44c, 60.45c, 60.46c, or 60.47c) during periods of combustion research, as defined in §60.41c.

(d) Any temporary change to an existing steam generating unit for the purpose of conducting combustion research is not considered a modification under §60.14.

[55 FR 37683, Sept. 12, 1990, as amended at 61 FR 20736, May 8, 1996]

§ 60.41c Definitions.

As used in this subpart, all terms not defined herein shall have the meaning given them in the Clean Air Act and in subpart A of this part.

Annual capacity factor means the ratio between the actual heat input to a steam generating unit from an individual fuel or combination of fuels during a period of 12 consecutive calendar months and the potential heat input to the steam generating unit from all fuels had the steam ch a separate source (such as a stationary gas turbine, internal combustion engine, or kiln) provides exhaust gas to a steam generating unit.

Coal means all solid fuels classified as anthracite, bituminous, subbituminous, or lignite by the American Society for Testing and Materials in ASTM D388–77, ''Standard Specification for Classification of Coals by Rank'' (incorporated by reference—see §60.17); coal refuse; and petroleum coke. Synthetic fuels derived from coal for the purpose of creating useful heat, including but not limited to solvent-refined coal, gasified coal, coal-oil mixtures, and coal-water mixtures, are included in this definition for the purposes of this subpart.

Coal refuse means any by-product of coal mining or coal cleaning operations with an ash content greater than 50 percent (by weight) and a heating value less than 13,900 kilojoules per kilogram (kJ/kg) (6,000 Btu per pound (Btu/lb) on a dry basis.

Cogeneration steam generating unit means a steam generating unit that simultaneously produces both electrical (or mechanical) and thermal energy from the same primary energy source.

Combined cycle system means a system in which a separate source (such as a stationary gas turbine, internal combustion engine, or kiln) provides exhaust gas to a steam generating unit.

Combustion research means the experimental firing of any fuel or combination of fuels in a steam generating unit for the purpose of conducting research and development of more efficient combustion or more effective prevention or control of air pollutant emissions from combustion, provided that, during these periods of research and development, the heat generated is not used for any purpose other than preheating combustion air for use by that steam generating unit (i.e., the heat generated is released to the atmosphere without being used for space heating, process heating, driving pumps, preheating combustion air for other units, generating electricity, or any other purpose).

Conventional technology means wet flue gas desulfurization technology, dry flue gas desulfurization technology, atmospheric fluidized bed combustion technology, and oil hydrodesulfurization technology.

Distillate oil means fuel oil that complies with the specifications for fuel oil numbers 1 or 2, as defined by the American Society for Testing and Materials in ASTM D396–78, ''Standard Specification for Fuel Oils'' (incorporated by reference—see §60.17).

Dry flue gas desulfurization technology means a sulfur dioxide (SO_2) control system that is located between the steam generating unit and the exhaust vent or stack, and that removes sulfur oxides from the combustion gases of the steam generating unit by contacting the combustion gases with an alkaline slurry or solution and forming a dry powder material. This definition includes devices where the dry powder material is subsequently converted to another form. Alkaline reagents used in dry flue gas desulfurization systems include, but are not limited to, lime and sodium compounds.

Duct burner means a device that combusts fuel and that is placed in the exhaust duct from another source (such as a stationary gas turbine, internal combustion engine, kiln, etc.) to allow the firing of additional fuel to heat the exhaust gases before the exhaust gases enter a steam generating unit.

Emerging technology means any SO_2 control system that is not defined as a conventional technology under this section, and for which the owner or operator of the affected facility has received approval from the Administrator to operate as an emerging technology under §60.48c(a)(4).

Federally enforceable means all limitations and conditions that are enforceable by the Administrator, including the requirements of 40 CFR Parts 60 and 61, requirements within any applicable State implementation plan, and any permit requirements established under 40 CFR 52.21 or under 40 CFR 51.18 and 40 CFR 51.24.

Fluidized bed combustion technology means a device wherein fuel is distributed onto a bed (or series of beds) of limestone aggregate (or other sorbent materials) for combustion; and these materials are forced upward in the device by the flow of combustion air and the gaseous products of combustion. Fluidized bed combustion technology includes, but is not limited to, bubbling bed units and circulating bed units.

Fuel pretreatment means a process that removes a portion of the sulfur in a fuel before combustion of the fuel in a steam generating unit.

Heat input means heat derived from combustion of fuel in a steam generating unit and does not include the heat derived from preheated combustion air, recirculated flue gases, or exhaust gases from other sources (such as stationary gas turbines, internal combustion engines, and kilns).

Heat transfer medium means any material that is used to transfer heat from one point to another point.

Maximum design heat input capacity means the ability of a steam generating unit to combust a stated maximum amount of fuel (or combination of fuels) on a steady state basis as determined by the physical design and characteristics of the steam generating unit.

Natural gas means (1) a naturally occurring mixture of hydrocarbon and nonhydrocarbon gases found in geologic formations beneath the earth's surface, of which the principal constituent is methane, or (2) liquefied petroleum (LP) gas, as defined by the American Society for Testing and Materials in ASTM D1835–86, ''Standard Specification for Liquefied Petroleum

Gases'' (incorporated by reference—see § 60.17).

Noncontinental area means the State of Hawaii, the Virgin Islands, Guam, American Samoa, the Commonwealth of Puerto Rico, or the Northern Mariana Islands.

Oil means crude oil or petroleum, or a liquid fuel derived from crude oil or petroleum, including distillate oil and residual oil.

Potential sulfur dioxide emission rate means the theoretical SO_2 emissions (nanograms per joule [ng/J], or pounds per million Btu [lb/million Btu] heat input) that would result from combusting fuel in an uncleaned state and without using emission control systems.

Process heater means a device that is primarily used to heat a material to initiate or promote a chemical reaction in which the material participates as a reactant or catalyst.

Residual oil means crude oil, fuel oil that does not comply with the specifications under the definition of distillate oil, and all fuel oil numbers 4, 5, and 6, as defined by the American Society for Testing and Materials in ASTM D396–78, ''Standard Specification for Fuel Oils'' (incorporated by reference—see § 60.17).

Steam generating unit means a device that combusts any fuel and produces steam or heats water or any other heat transfer medium. This term includes any duct burner that combusts fuel and is part of a combined cycle system. This term does not include process heaters as defined in this subpart.

Steam generating unit operating day means a 24-hour period between 12:00 midnight and the following midnight during which any fuel is combusted at any time in the steam generating unit. It is not necessary for fuel to be combusted continuously for the entire 24-hour period.

Wet flue gas desulfurization technology means an SO_2 control system that is located between the steam generating unit and the exhaust vent or stack, and that removes sulfur oxides from the combustion gases of the steam generating unit by contacting the combustion gases with an alkaline slurry or solution and forming a liquid material. This definition includes devices where the liquid material is subsequently converted to another form. Alkaline reagents used in wet flue gas desulfurization systems include, but are not limited to, lime, limestone, and sodium compounds.

Wet scrubber system means any emission control device that mixes an aqueous stream or slurry with the exhaust gases from a steam generating unit to control emissions of particulate matter (PM) or SO_2.

Wood means wood, wood residue, bark, or any derivative fuel or residue thereof, in any form, including but not limited to sawdust, sanderdust, wood chips, scraps, slabs, millings, shavings, and processed pellets made from wood or other forest residues.

[55 FR 37683, Sept. 12, 1990, as amended at 61 FR 20736, May 8, 1996]

§ 60.42c Standard for sulfur dioxide.

(a) Except as provided in paragraphs (b), (c), and (e) of this section, on and after the date on which the initial performance test is completed or required to be completed under § 60.8 of this part, whichever date comes first, the owner the operator of an affected facility that combusts only coal shall neither: (1) cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of 10 percent (0.10) of the potential SO_2 emission rate (90 percent reduction); nor (2) cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of 520 ng/J (1.2 lb/million Btu) heat input. If coal is combusted with other fuels, the affected facility is subject to the 90 percent SO_2 reduction requirement specified in this paragraph and the emission limit is determined pursuant to paragraph (e)(2) of this section.

(b) Except as provided in paragraphs (c) and (e) of this section, on and after the date on which the initial performance test is completed or required to be completed under § 60.8 of this part, whichever date comes first, the owner or operator of an affected facility that:

(1) Combusts coal refuse alone in a fluidized bed combustion steam generating unit shall neither:

(i) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of

20 percent (0.20) of the potential SO_2 emission rate (80 percent reduction); nor

(ii) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of 520 ng/J (1.2 lb/million Btu) heat input. If coal is fired with coal refuse, the affected facility is subject to paragraph (a) of this section. If oil or any other fuel (except coal) is fired with coal refuse, the affected facility is subject to the 90 percent SO_2 reduction requirement specified in paragraph (a) of this section and the emission limit determined pursuant to paragraph (e)(2) of this section.

(2) Combusts only coal and that uses an emerging technology for the control of SO_2 emissions shall neither:

(i) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of 50 percent (0.50) of the potential SO_2 emission rate (50 percent reduction); nor

(ii) Cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of 260 ng/J (0.60 lb/million Btu) heat input. If coal is combusted with other fuels, the affected facility is subject to the 50 percent SO_2 reduction requirement specified in this paragraph and the emission limit determined pursuant to paragraph (e)(2) of this section.

(c) On and after the date on which the initial performance test is completed or required to be completed under §60.8 of this part, whichever date comes first, no owner or operator of an affected facility that combusts coal, alone or in combination with any other fuel, and is listed in paragraphs (c)(1), (2), (3), or (4) of this section shall cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of the emission limit determined pursuant to paragraph (e)(2) of this section. Percent reduction requirements are not applicable to affected facilities under this paragraph.

(1) Affected facilities that have a heat input capacity of 22 MW (75 million Btu/hr) or less.

(2) Affected facilities that have an annual capacity for coal of 55 percent (0.55) or less and are subject to a Federally enforceable requirement limiting operation of the affected facility to an annual capacity factor for coal of 55 percent (0.55) or less.

(3) Affected facilities located in a noncontinental area.

(4) Affected facilities that combust coal in a duct burner as part of a combined cycle system where 30 percent (0.30) or less of the heat entering the steam generating unit is from combustion of coal in the duct burner and 70 percent (0.70) or more of the heat entering the steam gen erating unit is from exhaust gases entering the duct burner.

(d) On and after the date on which the initial performance test is completed or required to be completed under §60.8 of this part, whichever date comes first, no owner or operator of an affected facility that combusts oil shall cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of 215 ng/J (0.50 lb/million Btu) heat input; or, as an alternative, no owner or operator of an affected facility that combusts oil shall combust oil in the affected facility that contains greater than 0.5 weight percent sulfur. The percent reduction requirements are not applicable to affected facilities under this paragraph.

(e) On and after the date on which the initial performance test is completed or required to be completed under §60.8 of this part, whichever date comes first, no owner or operator of an affected facility that combusts coal, oil, or coal and oil with any other fuel shall cause to be discharged into the atmosphere from that affected facility any gases that contain SO_2 in excess of the following:

(1) The percent of potential SO_2 emission rate required under paragraph (a) or (b)(2) of this section, as applicable, for any affected facility that

(i) Combusts coal in combination with any other fuel,

(ii) Has a heat input capacity greater than 22 MW (75 million Btu/hr), and

(iii) Has an annual capacity factor for coal greater than 55 percent (0.55); and

(2) The emission limit determined according to the following formula for any affected facility that combusts

coal, oil, or coal and oil with any other fuel:

$$E_s=(K_a H_a+K_b H_b+K_c H_c)/H_a+H_b+H_c)$$

where:

E_s is the SO_2 emission limit, expressed in ng/J or lb/million Btu heat input,

K_a is 520 ng/J (1.2 lb/million Btu),

K_b is 260 ng/J (0.60 lb/million Btu),

K_c is 215 ng/J (0.50 lb/million Btu),

H_a is the heat input from the combustion of coal, except coal combusted in an affected facility subject to paragraph (b)(2) of this section, in Joules (J) [million Btu]

H_b is the heat input from the combustion of coal in an affected facility subject to paragraph (b)(2) of this section, in J (million Btu)

H_c is the heat input from the combustion of oil, in J (million Btu).

(f) Reduction in the potential SO_2 emission rate through fuel pretreatment is not credited toward the percent reduction requirement under paragraph (b)(2) of this section unless:

(1) Fuel pretreatment results in a 50 percent (0.50) or greater reduction in the potential SO_2 emission rate; and

(2) Emissions from the pretreated fuel (without either combustion or post-combustion SO_2 control) are equal to or less than the emission limits specified under paragraph (b)(2) of this section.

(g) Except as provided in paragraph (h) of this section, compliance with the percent reduction requirements, fuel oil sulfur limits, and emission limits of this section shall be determined on a 30-day rolling average basis.

(h) For affected facilities listed under paragraphs (h)(1), (2), or (3) of this section, compliance with the emission limits or fuel oil sulfur limits under this section may be determined based on a certification from the fuel supplier, as described under §60.48c(f)(1), (2), or (3), as applicable.

(1) Distillate oil-fired affected facilities with heat input capacities between 2.9 and 29 MW (10 and 100 million Btu/hr).

(2) Residual oil-fired affected facilities with heat input capacities between 2.9 and 8.7 MW (10 and 30 million Btu/hr).

(3) Coal-fired facilities with heat input capacities between 2.9 and 8.7 MW (10 and 30 million Btu/hr).

(i) The SO_2 emission limits, fuel oil sulfur limits, and percent reduction requirements under this section apply at all times, including periods of startup, shutdown, and malfunction.

(j) Only the heat input supplied to the affected facility from the combustion of coal and oil is counted under this section. No credit is provided for the heat input to the affected facility from wood or other fuels or for heat derived from exhaust gases from other sources, such as stationary gas turbines, internal combustion engines, and kilns.

§60.43c Standard for particulate matter.

(a) On and after the date on which the initial performance test is completed or required to be completed under §60.8 of this part, whichever date comes first, no owner or operator of an affected facility that combusts coal or combusts mixtures of coal with other fuels and has a heat input capacity of 8.7 MW (30 million Btu/hr) or greater, shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in excess of the following emission limits:

(1) 22 ng/J (0.05 lb/million Btu) heat input if the affected facility combusts only coal, or combusts coal with other fuels and has an annual capacity factor for the other fuels of 10 percent (0.10) or less.

(2) 43 ng/J (0.10 lb/million Btu) heat imput if the affected facility combusts coal with other fuels, has an annual capacity factor for the other fuels greater than 10 percent (0.10), and is subject to a federally enforceable requirement limiting operation of the affected facility to an annual capacity factor greater than 10 percent (0.10) for fuels other than coal.

(b) On and after the date on which the initial performance test is completed or required to be completed under §60.8 of this part, whichever date comes first, no owner or operator of an affected facility that combusts wood or combusts mixtures of wood with other fuels (except coal) and has a heat input capacity of 8.7 MW (30 million Btu/hr) or greater, shall cause to be discharged into the atmosphere from that affected facility any gases that contain PM in

excess of the following emissions limits:

(1) 43 ng/J (0.10 lb/million Btu) heat input if the affected facility has an annual capacity factor for wood greater than 30 percent (0.30); or

(2) 130 ng/J (0.30 lb/million Btu) heat input if the affected facility has an annual capacity factor for wood of 30 percent (0.30) or less and is subject to a federally enforceable requirement limiting operation of the affected facility to an annual capacity factor for wood of 30 percent (0.30) or less.

(c) On and after the date on which the initial performance test is completed or required to be completed under §60.8 of this part, whichever date comes first, no owner or operator of an affected facility that combusts coal, wood, or oil and has a heat input capacity of 8.7 MW (30 million Btu/hr) or greater shall cause to be discharged into the atmosphere from that affected facility any gases that exhibit greater than 20 percent opacity (6-minute average), except for one 6-minute period per hour of not more than 27 percent opacity.

(d) The PM and opacity standards under this section apply at all times, except during periods of startup, shutdown, or malfunction.

§60.44c Compliance and performance test methods and procedures for sulfur dioxide.

(a) Except as provided in paragraphs (g) and (h) of this section and in §60.8(b), performance tests required under §60.8 shall be conducted following the procedures specified in paragraphs (b), (c), (d), (e), and (f) of this section, as applicable. Section 60.8(f) does not apply to this section. The 30-day notice required in §60.8(d) applies only to the initial performance test unless otherwise specified by the Administrator.

(b) The initial performance test required under §60.8 shall be conducted over 30 consecutive operating days of the steam generating unit. Compliance with the percent reduction requirements and SO_2 emission limits under §60.42c shall be determined using a 30-day average. The first operating day included in the initial performance test shall be scheduled within 30 days after achieving the maximum production rate at which the affect facility will be operated, but not later than 180 days after the initial startup of the facility. The steam generating unit load during the 30-day period does not have to be the maximum design heat input capacity, but must be representative of future operating conditions.

(c) After the initial performance test required under paragraph (b) and §60.8, compliance with the percent reduction requirements and SO_2 emission limits under §60.42c is based on the average percent reduction and the average $S0_2$ emission rates for 30 consecutive steam generating unit operating days. A separate performance test is completed at the end of each steam generating unit operating day, and a new 30-day average percent reduction and SO_2 emission rate are calculated to show compliance with the standard.

(d) If only coal, only oil, or a mixture of coal and oil is combusted in an affected facility, the procedures in Method 19 are used to determine the hourly SO_2 emission rate (E_{ho}) and the 30-day average SO_2 emission rate (E_{ao}). The hourly averages used to compute the 30-day averages are obtained from the continuous emission monitoring system (CEMS). Method 19 shall be used to calculate E_{ao} when using daily fuel sampling or Method 6B.

(e) If coal, oil, or coal and oil are combusted with other fuels:

(1) An adjusted E_{ho} ($E_{ho}o$) is used in Equation 19–19 of Method 19 to compute the adjusted E_{ao} ($E_{ao}o$). The $E_{ho}o$ is computed using the following formula:

$$E_{ho}o=[E_{ho}-E_w(1-X_k)]/X_k$$

where:

$E_{ho}o$ is the adjusted E_{ho}, ng/J (lb/million Btu)

E_{ho} is the hourly SO_2 emission rate, ng/J (lb/million Btu)

E_w is the SO_2 concentration in fuels other than coal and oil combusted in the affected facility, as determined by fuel sampling and analysis procedures in Method 9, ng/J (lb/million Btu). The value E_w for each fuel lot is used for each hourly average during the time that the lot is being combusted. The owner or operator does not have to measure E_w if the owner or operator elects to assume E_w=0.

X_k is the fraction of the total heat input from fuel combustion derived from coal and oil, as determined by applicable procedures in Method 19.

(2) The owner or operator of an affected facility that qualifies under the provisions of §60.42c(c) or (d) [where percent reduction is not required] does not have to measure the parameters E_w or X_k if the owner or operator of the affected facility elects to measure emission rates of the coal or oil using the fuel sampling and analysis procedures under Method 19.

(f) Affected facilities subject to the percent reduction requirements under §60.42c(a) or (b) shall determine compliance with the SO_2 emission limits under §60.42c pursuant to paragraphs (d) or (e) of this section, and shall determine compliance with the percent reduction requirements using the following procedures:

(1) If only coal is combusted, the percent of potential SO_2 emission rate is computed using the following formula:

$$\%P_s = 100(1 - \%R_g/100)(1 - \%R_f/100)$$

where

$\%P_s$ is the percent of potential SO_2 emission rate, in percent

$\%R_g$ is the SO_2 removal efficiency of the control device as determined by Method 19, in percent

$\%R_f$ is the SO_2 removal efficiency of fuel pretreatment as determined by Method 19, in percent

(2) If coal, oil, or coal and oil are combusted with other fuels, the same procedures required in paragraph (f)(1) of this section are used, except as provided for in the following:

(i) To compute the $\%P_s$, an adjusted $\%R_g$ ($\%R_go$) is computed from $E_{ao}o$ from paragraph (e)(1) of this section and an adjusted average SO_2 inlet rate ($E_{ai}o$) using the following formula:

$$\%R_go = 100\,[1.0 - E_{ao}o/E_{ai}o)]$$

where:

$\%R_go$ is the adjusted $\%R_g$, in percent

$E_{ao}o$ is the adjusted E_{ao}, ng/J (lb/million Btu)

$E_{ai}o$ is the adjusted average SO_2 inlet rate, ng/J (lb/million Btu)

(ii) To compute $E_{ai}o$, an adjusted hourly SO_2 inlet rate ($E_{hi}o$) is used. The $E_{hi}o$ is computed using the following formula:

$$E_{hi}o = [E_{hi} - E_w\,(1 - X_k)]/X_k$$

where:

$E_{hi}o$ is the adjusted E_{hi}, ng/J (lb/million Btu)

E_{hi} is the hourly SO_2 inlet rate, ng/J (lb/million Btu)

E_w is the SO_2 concentration in fuels other than coal and oil combusted in the affected facility, as determined by fuel sampling and analysis procedures in Method 19, ng/J (lb/million Btu). The value E_w for each fuel lot is used for each hourly average during the time that the lot is being combusted. The owner or operator does not have to measure E_w if the owner or operator elects to assume E_w = O.

X_k is the fraction of the total heat input from fuel combustion derived from coal and oil, as determined by applicable procedures in Method 19.

(g) For oil-fired affected facilities where the owner or operator seeks to demonstrate compliance with the fuel oil sulfur limits under §60.42c based on shipment fuel sampling, the initial performance test shall consist of sampling and analyzing the oil in the initial tank of oil to be fired in the steam generating unit to demonstrate that the oil contains 0.5 weight percent sulfur or less. Thereafter, the owner or operator of the affected facility shall sample the oil in the fuel tank after each new shipment of oil is received, as described under §60.46c(d)(2).

(h) For affected facilities subject to §60.42c(h)(1), (2), or (3) where the owner or operator seeks to demonstrate compliance with the SO_2 standards based on fuel supplier certification, the performance test shall consist of the certification, the certification from the fuel supplier, as described under §60.48c(f)(1), (2), or (3), as applicable.

(i) The owner or operator of an affected facility seeking to demonstrate compliance with the SO_2 standards under §60.42c(c)(2) shall demonstrate the maximum design heat input capacity of the steam generating unit by operating the steam generating unit at this capacity for 24 hours. This demonstration shall be made during the initial performance test, and a subsequent demonstration may be requested at any other time. If the demonstrated 24-hour averaged firing rate for the affected facility is less than the maximum design heat input capacity stated by the manufacturer of the affected facility, the demonstrated 24-hour average firing rate shall be used to determine the annual capacity factor for the

affected facility; otherwise, the maximum design heat input capacity provided by the manufacturer shall be used.

(j) The owner or operator of an affected facility shall use all valid SO_2 emissions data in calculating $\%P_s$ and E_{ho} under paragraphs (d), (e), or (f) of this section, as applicable, whether or not the minimum emissions data requirements under § 60.46c(f) are achieved. All valid emissions data, including valid data collected during periods of startup, shutdown, and malfunction, shall be used in calculating $\%P_s$ or E_{ho} pursuant to paragraphs (d), (e), or (f) of this section, as applicable.

§ 60.45c Compliance and performance test methods and procedures for particulate matter.

(a) The owner or operator of an affected facility subject to the PM and/or opacity standards under § 60.43c shall conduct an initial performance test as required under § 60.8, and shall conduct subsequent performance tests as requested by the Administrator, to determine compliance with the standards using the following procedures and reference methods.

(1) Method 1 shall be used to select the sampling site and the number of traverse sampling points. The sampling time for each run shall be at least 120 minutes and the minimum sampling volume shall be 1.7 dry square cubic meters (dscm) [60 dry square cubic feet (dscf)] except that smaller sampling times or volumes may be approved by the Administrator when necessitated by process variables or other factors.

(2) Method 3 shall be used for gas analysis when applying Method 5, Method 5B, of Method 17.

(3) Method 5, Method 5B, or Method 17 shall be used to measure the concentration of PM as follows:

(i) Method 5 may be used only at affected facilities without wet scrubber systems.

(ii) Method 17 may be used at affected facilities with or without wet scrubber systems provided the stack gas temperature does not exceed a temperature of 160 °C (320 °F). The procedures of Sections 2.1 and 2.3 of Method 5B may be used in Method 17 only if Method 17 is used in conjuction with a wet scrubber system. Method 17 shall not be used in conjuction with a wet scrubber system if the effluent is saturated or laden with water droplets.

(iii) Method 5B may be used in conjunction with a wet scrubber system.

(4) For Method 5 or Method 5B, the temperature of the sample gas in the probe and filter holder shall be monitored and maintained at 160 °C (320 °F).

(5) For determination of PM emissions, an oxygen or carbon dioxide measurement shall be obtained simultaneously with each run of Method 5, Method 5B, or Method 17 by traversing the duct at the same sampling location.

(6) For each run using Method 5, Method 5B, or Method 17, the emission rates expressed in ng/J (lb/million Btu) heat input shall be determined using:

(i) The oxygen or carbon dioxide measurements and PM measurements obtained under this section,

(ii) The dry basis F-factor, and

(iii) The dry basis emission rate calculation procedure contained in Method 19 (appendix A).

(7) Method 9 (6-minute average of 24 observations) shall be used for determining the opacity of stack emissions.

(b) The owner or operator of an affected facility seeking to demonstrate compliance with the PM standards under § 60.43c(b)(2) shall demonstrate the maximum design heat input capacity of the steam generating unit by operating the steam generating unit at this capacity for 24 hours. This demonstration shall be made during the initial performance test, and a subsequent demonstration may be requested at any other time. If the demonstrated 24-hour average firing rate for the affected facility is less than the maximum design heat input capacity stated by the manufacturer of the affected facility, the demonstrated 24-hour average firing rate shall be used to determine the annual capacity factor for the affected facility; otherwise, the maximum design heat input capacity provided by the manufacturer shall be used.

§ 60.46c Emission monitoring for sulfur dioxide

(a) Except as provided in paragraphs (d) and (e) of this section, the owner or

operator of an affected facility subject to the SO_2 emission limits under § 60.42c shall install, calibrate, maintain, and operate a CEMS for measuring SO_2 concentrations and either oxygen or carbon dioxide concentrations at the outlet of the SO_2 control device (or the outlet of the steam generating unit if no SO_2 control device is used), and shall record the output of the system. The owner or operator of an affected facility subject to the percent reduction requirements under § 60.42c shall measure SO_2 concentrations and either oxygen or carbon dioxide concentrations at both the inlet and outlet of the SO_2 control device.

(b) The 1-hour average SO_2 emission rates measured by a CEM shall be expressed in ng/J or lb/million Btu heat input and shall be used to calculate the average emission rates under § 60.42c. Each 1-hour average SO_2 emission rate must be based on at least 30 minutes of operation and include at least 2 data points representing two 15-minute periods. Hourly SO_2 emission rates are not calculated if the affected facility is operated less than 30 minutes in a 1-hour period and are not counted toward determination of a steam generating unit operating day.

(c) The procedures under § 60.13 shall be followed for installation, evaluation, and operation of the CEMS.

(1) All CEMS shall be operated in accordance with the applicable procedures under Performance Specifications 1, 2, and 3 (appendix B).

(2) Quarterly accuracy determinations and daily calibration drift tests shall be performed in accordance with Procedure 1 (appendix F).

(3) For affected facilities subject to the percent reduction requirements under § 60.42c, the span value of the SO_2 CEMS at the inlet to the SO_2 control device shall be 125 percent of the maximum estimated hourly potential SO_2 emission rate of the fuel combusted, and the span value of the SO_2 CEMS at the outlet from the SO_2 control device shall be 50 percent of the maximum estimated hourly potential SO_2 emission rate of the fuel combusted.

(4) For affected facilities that are not subject to the percent reduction requirements of § 60.42c, the span value of the SO_2 CEMS at the outlet from the SO_2 control device (or outlet of the steam generating unit if no SO_2 control device is used) shall be 125 percent of the maximum estimated hourly potential SO_2 emission rate of the fuel combusted.

(d) As an alternative to operating a CEMS at the inlet to the SO_2 control device (or outlet of the steam generating unit if no SO_2 control device is used) as required under paragraph (a) of this section, an owner or operator may elect to determine the average SO_2 emission rate by sampling the fuel prior to combustion. As an alternative to operating a CEM at the outlet from the SO_2 control device (or outlet of the steam generating unit if no SO_2 control device is used) as required under paragraph (a) of this section, an owner or operator may elect to determine the average SO_2 emission rate by using Method 6B. Fuel sampling shall be conducted pursuant to either paragraph (d)(1) or (d)(2) of this section. Method 6B shall be conducted pursuant to paragraph (d)(3) of this section.

(1) For affected facilities combusting coal or oil, coal or oil samples shall be collected daily in an as-fired condition at the inlet to the steam generating unit and analyzed for sulfur content and heat content according the Method 19. Method 19 provides procedures for converting these measurements into the format to be used in calculating the average SO_2 input rate.

(2) As an alternative fuel sampling procedure for affected facilities combusting oil, oil samples may be collected from the fuel tank for each steam generating unit immediately after the fule tank is filled and before any oil is combusted. The owner or operator of the affected facility shall analyze the oil sample to determine the sulfur content of the oil. If a partially empty fuel tank is refilled, a new sample and analysis of the fuel in the tank would be required upon filling. Results of the fuel analysis taken after each new shipment of oil is received shall be used as the daily value when calculating the 30-day rolling average until the next shipment is received. If the fuel analysis shows that the sulfur content in the fuel tank is greater than 0.5 weight percent sulfur, the owner or operator shall ensure that the sulfur

content of subsequent oil shipments is low enough to cause the 30-day rolling average sulfur content to be 0.5 weight percent sulfur or less.

(3) Method 6B may be used in lieu of CEMS to measure SO_2 at the inlet or outlet of the SO_2 control system. An initial stratification test is required to verify the adequacy of the Method 6B sampling location. The stratification test shall consist of three paired runs of a suitable SO_2 and carbon dioxide measurement train operated at the candidate location and a second similar train operated according to the procedures in §3.2 and the applicable procedures in section 7 of Performance Specification 2 (appendix B). Method 6B, Method 6A, or a combination of Methods 6 and 3 or Methods 6C and 3A are suitable measurement techniques. If Method 6B is used for the second train, sampling time and timer operation may be adjusted for the stratification test as long as an adequate sample volume is collected; however, both sampling trains are to be operated similarly. For the location to be adequate for Method 6B 24-hour tests, the mean of the absolute difference between the three paired runs must be less than 10 percent (0.10).

(e) The monitoring requirements of paragraphs (a) and (d) of this section shall not apply to affected facilities subject to §60.42c(h) (1), (2), or (3) where the owner or operator of the affected facility seeks to demonstrate compliance with the SO_2 standards based on fuel supplier certification, as described under §60.48c(f) (1), (2), or (3), as applicable.

(f) The owner or operator of an affected facility operating a CEMS pursuant to paragraph (a) of this section, or conducting as-fired fuel sampling pursuant to paragraph (d)(1) of this section, shall obtain emission data for at least 75 percent of the operating hours in at least 22 out of 30 successive steam generating unit operating days. If this minimum data requirement is not met with a single monitoring system, the owner or operator of the affected facility shall supplement the emission data with data collected with other monitoring systems as approved by the Administrator.

§ 60.47c Emission monitoring for particulate matter.

(a) The owner or operator of an affected facility combusting coal, residual oil, or wood that is subject to the opacity standards under §60.43c shall install, calibrate, maintain, and operate a CEMS for measuring the opacity of the emissions discharged to the atmosphere and record the output of the system.

(b) All CEMS for measuring opacity shall be operated in accordance with the applicable procedures under Performance Specification 1 (appendix B). The span value of the opacity CEMS shall be between 60 and 80 percent.

§ 60.48c Reporting and recordkeeping requirements.

(a) The owner or operator of each affected facility shall submit notification of the date of construction or reconstruction, anticipated startup, and actual startup, as provided by §60.7 of this part. This notification shall include:

(1) The design heat input capacity of the affected facility and identification of fuels to be combusted in the affected facility.

(2) If applicable, a copy of any Federally enforceable requirement that limits the annual capacity factor for any fuel or mixture of fuels under §60.42c, or §60.43c.

(3) The annual capacity factor at which the owner or operator anticipates operating the affected facility based on all fuels fired and based on each individual fuel fired.

(4) Notification if an emerging technology will be used for controlling SO_2 emissions. The Administrator will examine the description of the control device and will determine whether the technology qualifies as an emerging technology. In making this determination, the Administrator may require the owner or operator of the affected facility to submit additional information concerning the control device. The affected facility is subject to the provisions of §60.42c(a) or (b)(1), unless and until this determination is made by the Administrator.

(b) The owner or operator of each affected facility subject to the SO_2 emission limits of §60.42c, or the PM or

opacity limits of § 60.43c, shall submit to the Administrator the performance test data from the initial and any subsequent performance tests and, if applicable, the performance evaluation of the CEMS using the applicable performance specifications in appendix B.

(c) The owner or operator of each coal-fired, residual oil-fired, or wood-fired affected facility subject to the opacity limits under § 60.43c(c) shall submit excess emission reports for any excess emissions from the affected facility which occur during the reporting period.

(d) The owner or operator of each affected facility subject to the SO_2 emission limits, fuel oil sulfur limits, or percent reduction requirements under § 60.42c shall submit reports to the Administrator.

(e) The owner or operator of each affected facility subject to the SO_2 emission limits, fuel oil sulfur limits, or percent reduction requirements under § 60.43c shall keep records and submit reports as required under paragraph (d) of this section, including the following information, as applicable.

(1) Calendar dates covered in the reporting period.

(2) Each 30-day average SO_2 emission rate (nj/J or lb/million Btu), or 30-day average sulfur content (weight percent), calculated during the reporting period, ending with the last 30-day period; reasons for any noncompliance with the emission standards; and a description of corrective actions taken.

(3) Each 30-day average percent of potential SO_2 emission rate calculated during the reporting period, ending with the last 30-day period; reasons for any noncompliance with the emission standards; and a description of the corrective actions taken.

(4) Identification of any steam generating unit operating days for which SO_2 or diluent (oxygen or carbon dioxide) data have not been obtained by an approved method for at least 75 percent of the operating hours; justification for not obtaining sufficient data; and a description of corrective actions taken.

(5) Identification of any times when emissions data have been excluded from the calculation of average emission rates; justification for excluding data; and a description of corrective actions taken if data have been excluded for periods other than those during which coal or oil were not combusted in the steam generating unit.

(6) Identification of the F factor used in calculations, method of determination, and type of fuel combusted.

(7) Identification of whether averages have been obtained based on CEMS rather than manual sampling methods.

(8) If a CEMS is used, identification of any times when the pollutant concentration exceeded the full span of the CEMS.

(9) If a CEMS is used, description of any modifications to the CEMS that could affect the ability of the CEMS to comply with Performance Specifications 2 or 3 (appendix B).

(10) If a CEMS is used, results of daily CEMS drift tests and quarterly accuracy assessments as required under appendix F, Procedure 1.

(11) If fuel supplier certification is used to demonstrate compliance, records of fuel supplier certification is used to demonstrate compliance, records of fuel supplier certification as described under paragraph (f)(1), (2), or (3) of this section, as applicable. In addition to records of fuel supplier certifications, the report shall include a certified statement signed by the owner or operator of the affected facility that the records of fuel supplier certifications submitted represent all of the fuel combusted during the reporting period.

(f) Fuel supplier certification shall include the following information:

(1) For distillate oil:

(i) The name of the oil supplier; and

(ii) A statement from the oil supplier that the oil complies with the specifications under the definition of distillate oil in § 60.41c.

(2) For residual oil:

(i) The name of the oil supplier;

(ii) The location of the oil when the sample was drawn for analysis to determine the sulfur content of the oil, specifically including whether the oil was sampled as delivered to the affected facility, or whether the sample was drawn from oil in storage at the oil supplier's or oil refiner's facility, or other location;

(iii) The sulfur content of the oil from which the shipment came (or of the shipment itself); and

(iv) The method used to determine the sulfur content of the oil.

(3) For coal:

(i) The name of the coal supplier;

(ii) The location of the coal when the sample was collected for analysis to determine the properties of the coal, specifically including whether the coal was sampled as delivered to the affected facility or whether the sample was collected from coal in storage at the mine, at a coal preparation plant, at a coal supplier's facility, or at another location. The certification shall include the name of the coal mine (and coal seam), coal storage facility, or coal preparation plant (where the sample was collected);

(iii) The results of the analysis of the coal from which the shipment came (or of the shipment itself) including the sulfur content, moisture content, ash content, and heat content; and

(iv) The methods used to determine the properties of the coal.

(g) The owner or operator of each affected facility shall record and maintain records of the amounts of each fuel combusted during each day.

(h) The owner or operator of each affected facility subject to a Federally enforceable requirement limiting the annual capacity factor for any fuel or mixture of fuels under §60.42c or §60.43c shall calculate the annual capacity factor individually for each fuel combusted. The annual capacity factor is determined on a 12-month rolling average basis with a new annual capacity factor calculated at the end of the calendar month.

(i) All records required under this section shall be maintained by the owner or operator of the affected facility for a period of two years following the date of such record.

(j) The reporting period for the reports required under this subpart is each six-month period. All reports shall be submitted to the Administrator and shall be postmarked by the 30th day following the end of the reporting period.

[55 FR 37683, Sept. 12, 1990, as amended at 64 FR 7465, Feb. 12, 1999]

Subpart E—Standards of Performance for Incinerators

§ 60.50 Applicability and designation of affected facility.

(a) The provisions of this subpart are applicable to each incinerator of more than 45 metric tons per day charging rate (50 tons/day), which is the affected facility.

(b) Any facility under paragraph (a) of this section that commences construction or modification after August 17, 1971, is subject to the requirements of this subpart.

[42 FR 37936, July 25, 1977]

§ 60.51 Definitions.

As used in this subpart, all terms not defined herein shall have the meaning given them in the Act and in subpart A of this part.

(a) *Incinerator* means any furnace used in the process of burning solid waste for the purpose of reducing the volume of the waste by removing combustible matter.

(b) *Solid waste* means refuse, more than 50 percent of which is municipal type waste consisting of a mixture of paper, wood, yard wastes, food wastes, plastics, leather, rubber, and other combustibles, and noncombustible materials such as glass and rock.

(c) *Day* means 24 hours.

[36 FR 24877, Dec. 23, 1971, as amended at 39 FR 20792, June 14, 1974]

§ 60.52 Standard for particulate matter.

(a) On and after the date on which the performance test required to be conducted by §60.8 is completed, no owner or operator subject to the provisions of this part shall cause to be discharged into the atmosphere from any affected facility any gases which contain particulate matter in excess of 0.18 g/dscm (0.08 gr/dscf) corrected to 12 percent CO_2.

[39 FR 20792, June 14, 1974]

§ 60.53 Monitoring of operations.

(a) The owner or operator of any incinerator subject to the provisions of this part shall record the daily charging rates and hours of operation.